IN THE UNITED STATES DISTRICT COURT

DISTRICT OF MINNESOTA

IN RE:

VIAGRA PRODUCTS LIABILITY LITIGATION

THIS DOCUMENT PERTAINS TO ALL CASES

MDL DOCKET NO. 1724

JUDGE PAUL A. MAGNUSON

VIDEOTAPED DEPOSITION OF DR. GERALD MCGWIN, JR.

S T I P U L A T I O N S

IT IS STIPULATED AND AGREED, by and between the parties through their respective counsel, that the deposition of:

DR. GERALD MCGWIN, JR.,

may be taken before Carrie M. Robinson, Certified Shorthand Reporter and Notary Public of the State of Alabama, at the Law Offices of Bradley, Arant, Rose & White, One Federal Place, 1819 5th Avenue North, Birmingham, Alabama, 35203, on the 14th day of June, 2007, commencing at approximately 8:15 a.m.

Condensed Copy

IT IS FURTHER STIPULATED AND AGREED that the signature to and reading of the deposition by the witness is waived, the deposition to have the same force and effect as if full compliance had been had with all laws and rules of Court relating to the taking of depositions.

IT IS FURTHER STIPULATED AND AGREED that it shall not be necessary for any objections to be made by counsel to any questions, except as to form or leading questions, and that counsel for the parties may make objections and assign grounds at the time of the trial, or at the time said deposition is offered in evidence, or prior thereto.

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I, Carrie M. Robinson, a Court Reporter of Birmingham, Alabama, and a Notary Public for the State of Alabama at Large, acting as Commissioner, certify that on this date, as provided by the Federal Rules of Civil Procedure and the foregoing stipulation of counsel, there came before me on the 14th day of June, 2007, at the law offices of Bradley, Arant, Rose & White, One Federal Place, 1819 5th Avenue North, Birmingham, Alabama 35203, commencing at approximately 8:15 a.m., DR. GERALD MCGWIN, JR., witness in the above cause, for oral examination, whereupon the following proceedings were had:

VIDEOGRAPHER: We are on the video record. My name is Donna Evans. I'm a Certified Legal Video Specialist with Bain & Associates Court Reporting in Birmingham, Alabama. Our address is 505 North 20th Street, Birmingham, Alabama. The date is June the 13th (sic), year 2007. The time is approximately 8:11 a.m.

We are in Birmingham, Alabama, at the law firm of Bradley, Arant, Rose & White. This case is entitled In Re Viagra Products Liability Litigation, filed in the United States District Court for the Southern District of Iowa (sic), MDL Number 06-1724.

The name of the witness is Dr. McGwin. He will be sworn, and the deposition will begin.

GERALD MCGWIN, JR., PH.D., being first duly sworn, was examined and testified as follows:

EXAMINATION BY MR. SLONIM:

Q Good morning, Dr. McGwin. How are you?

A I'm swell.

Q We had a chance to say hello this morning before the deposition. You understand that my name is Bert Slonim. I represent the defendant Pfizer in this action.

A Yes, sir.

Q Okay. Dr. McGwin, just for the record, would you state your full name and business address?

A Yes. Gerald McGwin, Jr. I have several addresses, but 1922 Seventh Avenue South, Suite 120, Birmingham, Alabama.

Q I'm going to mark as Deposition

Exhibit Number 1 a document that's been given to us as your curriculum vitae.

A Yes, sir.

(Deposition Exhibit Number 1 was marked for identification.)

Q Can you identify that as a current copy of your CV?

A Yes, sir.

Q Okay. I understand from the curriculum vitae that you received your Bachelor of Science degree from the University of Vermont in 1993; is that correct?

A Yes, sir.

Q And that you then went on and received a Master's of Science degree from Harvard in 1995; is that right?

A Yes, sir.

Q Dr. McGwin, one thing I should have mentioned before the deposition started, please give me a chance to complete my question before you begin your answer. And by the same token, I'll try to make sure that I give you a chance to complete your answer before I frame my next question. The court reporter needs to take down a transcript. And if we're too quick in

responding to each other, the court reporter can't get it down.
A My apologies.
Q Not at all. Thank you.
I understand then from your CV that you received a Ph.D. in epidemiology from the University of Birmingham in Alabama (sic) in the year 1998; is that right?
A Yes, sir.
Q Okay. And that you are currently employed as an Associate Professor of Epidemiology at the University of Alabama; is that right?
A Yes, sir.
Q Okay. Epidemiology is the science that studies the distribution and determinants of disease in a population; is that correct?
A Yes, sir.
Q Do you have a medical degree, Dr. McGwin?
A No, sir.
Q I take it you are not an ophthalmologist, a specialist in eye disorders?
A No, sir.
Q And that you are not licensed to

diagnose or treat patients; is that right?
A That is correct.
Q You understand that this case involves the prescription drug Viagra and an eye condition called nonarteritic anterior ischemic optic neuropathy; is that right?
A Correct.
Q Okay. And that condition which has the long name that I just said is often referred to by the acronym NAION; is that right?
A NAION or NAION is -- depending on how you want to pronounce it.
Q Okay. If I use the term "NAION," N-A-I-O-N, you understand that I'll be referring to nonarteritic anterior ischemic optic neuropathy, okay?
A Yes, sir.
Q Okay. Viagra is an oral medication that is used to treat erectile dysfunction; is that right?
A That is my understanding.
Q Okay. And Viagra works by inhibiting the action of an enzyme known as phosphodiesterase type 5; is that right?
A Not being a specialist in

pharmacology, I couldn't answer with any degree of certainty.
Q Have you heard of the term "PDE5 inhibitor"?
A Yes, sir.
Q And do you understand that Viagra is in the class of drugs that are called PDE5 inhibitors?
A That is my understanding.
Q Okay. And -- withdrawn.
Viagra was first approved for use as a medication in March of 1998; is that right?
A I don't know that for certainty.
Q Do you recall that it was in 1998, without regard to the month, that Viagra was first approved?
A I don't know that with certainty.
Q Okay.
MR. SLONIM: I'll ask counsel for a stipulation that Viagra was approved for use in the United States in March of 1998.
MR. OVERHOLTZ: That's fine.
I think Mr. Slonim is correct, it's 1998.
THE WITNESS: Sorry. I just --

MR. SLONIM: No, no, no.
MR. OVERHOLTZ: Just for purposes of the record, I'm sure.
MR. SLONIM: Yeah.
Q And do you understand that other medications for the treatment of erectile dysfunction that are also -- operate as or classified as PDE5 inhibitors were approved subsequent to Viagra?
A Yes, I believe that's true.
Q In other words, Viagra was the first one that was approved?
A That's correct.
Q Okay. And for purposes of this case as plaintiffs' counsel has stipulated, you should assume that Viagra was approved in March of 1998, okay?
A Yes, sir.
Q So in other words, Dr. McGwin, prior to March of 1998, Viagra was not available and in fact no PDE5 inhibitor was available, correct?
A Yes, sir.
Q But there were cases of NAION that were diagnosed before March of 1998; is that

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right?
A I don't know that for certainty.
Q You know that NAION existed as a medical disorder well before 1998, don't you?
A Yes.
Q Okay. In fact -- and we'll talk about this later -- in some of your work, you reference studies by Johnson and Arnold and Hattenhauer and other studies that talk about the incidence of NAION, and those were published well before 1998, correct?
A That is correct.
Q Okay. You agree with me that Viagra could not have caused any of the cases of NAION that occurred before the medication was on the market, correct?
A That is correct.
Q Whatever it was that caused the cases of NAION that occurred before March of 1998, it could not have been Viagra or any other of the oral ED medications, correct?
A That is correct.
Q Okay. Let's mark as the next deposition exhibit an article that you coauthored entitled "Frequency Doubling

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Technology Perimetry in Nonarteritic Ischemic Optic Neuropathy with Altitudinal Defects."
(Deposition Exhibit Number 2 was marked for identification.)
Q Dr. McGwin, can you identify this as an article that you coauthored?
A Yes, sir.
Q Okay. And I would like you to refer, please, to page 1278. It's about the fourth page in.
I will direct your attention, please, to the left-hand side. And do you see the first full paragraph that begins with the word "although"?
A Yes, sir.
Q Could you just read that paragraph out loud?
A The entire paragraph?
Q Yes.
A Yes, sir.
"Although there is no good experimental model of NAION, it is presumed that it represents a vascular disease of the optic disc. The rapid onset, poor recovery, and crowded appearance of the optic disc, and the

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association with microvascular diseases, such as hypertension and diabetes, support the widely held theory that vascular insufficiency of a structurally crowded optic disc leads to infarction of the laminar and possibly the retrolaminar optic nerve. In addition, it has been suggested that the altitudinal visual field defects seen in NAION are the result of infarctions of the optic disc that lie in the watershed zone between the distribution of the posterior ciliary arteries, possibly associated with nocturnal systemic hypotension."
Q Dr. McGwin, in that first sentence of that paragraph that you just read, when you state that there's no good experimental model of NAION, what do you mean?
A Not having written that sentence, sir, I can't necessarily translate it in that way.
Q Okay. That sentence is in a paper in which you are coauthored. Tell us what you and your coauthors were trying to communicate to the readers with that sentence.
A I believe what we were trying to convey is the fact that there is no commonly

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used animal model of NAION or an etiologic model of the disease, and that there are several hypotheses. And I believe Reference 10 is what has been cited here, that it represents a vascular problem, a vascular condition of the optic disc.
Q When you say there are hypotheses and then in your sentence, that first sentence when you say it is presumed that NAION is a vascular disease, you use the word "presume" because this is something that has not been scientifically proven; is that correct?
A That is correct.
Q Okay. And further down in that same paragraph when you say it's a widely held theory that NAION results from a vascular insufficiency -- do you see that?
A Yes, sir. I'm just reading the full sentence.
Q No, please. Let me start again just to make sure you are focused on what I'm asking.
When you and your coauthors note in this paragraph that it is a widely held theory that NAION results from a vascular insufficiency, you use the word "theory" to

communicate the information that this has not been scientifically proven that vascular insufficiency causes NAION, correct?
A That is correct.
Q And when you state that it has been suggested that certain visual field defects occurring in NAION result from infarction of certain blood vessels, you use the word "suggested" because it has not been scientifically proven that NAION results from infarction of those vessels, correct?
A Yes, sir.
Q And then farther down when you state that NAION is possibly associated with nocturnal systemic hypotension, you use the phrase "possibly associated" because it has not been scientifically proven that nocturnal systemic hypotension causes NAION, right?
MR. OVERHOLTZ: I object to form. It misstates the statement in the study that NAION was possibly associated with nocturnal hypotension.
THE COURT: It is overruled. You can answer the question if you are able.
Q Do you want to have it read back?

A Yeah. Yes, please.
Q Okay. The objection was overruled. I want to read back the question so you have it clearly in mind.
In the paragraph that you read out loud, there's a portion in which you say NAION is possibly associated with nocturnal systemic hypotension. You used the phrase "possibly associated" because it has not been scientifically proven that nocturnal systemic hypotension causes NAION, correct?
A That is correct.
Q And, Dr. McGwin, although there are theories about the cause of NAION, which you state in this paragraph, those theories have not been scientifically proven, correct?
A That is correct.
Q Now, we alluded to this at the beginning of the deposition, Dr. McGwin. There is a spontaneous background incidence of NAION in the general population, correct?
A Can I ask a question about your question? Is that --
Q If you don't -- if you don't understand my question, please.

A Okay. The word "spontaneous" is confusing to me.
Q Okay. And what is it that you don't understand about the word "spontaneous"?
A Well, when we're talking about the distribution or the occurrence of a disease in a population, the word "spontaneous" to me suggests accidental, erratic. And many diseases, in fact most diseases, perhaps if we exclude infectious diseases just for the moment, have a background incidence that is usually considered to be stable, perhaps barring some temporal fluctuations such as injuries and certain infectious diseases. So -- but that's --
Q Okay. Let me rephrase the question.
A Okay.
Q You agree that there is a background incidence of NAION in the general population that existed before Viagra or other ED medications ever came on the market, correct?
A That is correct.
Q Okay. And in fact, Dr. McGwin, in your own work, you have reported that an estimated 1500 to 6,000 people in the U.S. each

year develop NAION, correct?
A Which work are you specifically referring to?
Q Dr. McGwin, do you have your article in front of you?
A Yes, sir, right here (indicating).
Q We'll mark it later as a deposition exhibit.
MR. SLONIM: Oh, do you have it?
Q We will mark it right now.
A I'm sorry.
Q No problem.
(Deposition Exhibit Number 3 was marked for identification.)
Q We'll mark as Deposition Exhibit Number 3 an article by Dr. McGwin entitled "Non-Arteritic anterior ischaemic optic neuropathy and the treatment of erectile dysfunction."
Dr. McGwin, take a look, please, at the first two sentences of this paper. The first sentence you write: "Non-arteritic anterior ischaemic optic neuropathy is the most common optic neuropathy among older adults in the United States." Is that correct?

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A Yes, sir.
Q Okay. And in the next sentence, you say, "An estimated 1500 to 6,000 people will develop NAION annually." Is that correct?
A That is correct.
Q Okay. Does that refresh your recollection that in your own work that you have estimated that the background incidence of NAION is 1500 to 6,000 people per year in the U.S.?
A Those are not my personal estimates. They were obtained from the literature.
Q Right. But those are estimates that you referred to --
A Yes, sir, I referred to them, that's correct.
Q -- and quote in your own published work?
A Yes, sir.
Q Okay. And you cite in support of that, as you pointed out to me, some published literature references, correct? Those are references 4 to 6?
A Yes, sir.
Q And that's the Johnson and Arnold paper, the Hattenhauer paper, and also the AION Decompression Trial paper?
A Yes, sir.
Q Okay. Let's just mark those so we have them as exhibits.

(Deposition Exhibit Numbers 4-6 were marked for identification.)

Q Dr. McGwin, we've marked as Deposition Exhibit Number 4 a paper by Hattenhauer and others entitled "Incidence of Nonarteritic Anterior Ischemic Optic Neuropathy." We've marked as Deposition Exhibit Number 5 a paper by Johnson and Arnold entitled "Incidence of Nonarteritic and Arteritic Anterior Ischemic Optic Neuropathy," and we've marked as Deposition Exhibit Number 6 a paper by Newman and others entitled "The Fellow Eye in NAION: Report From the Ischemic Optic Neuropathy Decompression Trial Follow-Up Study," correct?
A Yes, sir.
Q And these are papers that you cited as references in support of the statement that 1500 to 6,000 people estimated in the United States develop NAION --
A Yes, sir.
Q -- per year?

Okay. And take a look just for a second at Exhibit Number 6. That's the AION Decompression Trial paper. In that first paragraph -- do you see that?
A Yes, sir.
Q And they have a similar sentence to yours at the bottom of that first paragraph that there were 1500 to 6,000 cases of NAION in the United States per year, correct?
A That is correct, sir.
Q Okay. And in the sentence before that, they say the annual incidence of NAION has been estimated from 2.3 to 10 per hundred thousand persons 50 years and older, correct?
A Yes, sir.
Q And they cite references 3 and 4?

Take a look at their references 3 and 4, please.
A Yes, sir.
Q Their references 3 and 4 are the Johnson and Arnold and the Hattenhauer papers, correct?
A That is correct.
Q And those are also the references that you cited?
A Yes, sir.
Q Okay. And it's correct that the Johnson and Arnold paper and the Hattenhauer paper report that the annual incidence of NAION ranges from 2.3 to 10.2 per hundred thousand for persons age 50 and older, correct?

MR. OVERHOLTZ: Object to the form of the question. It combines two studies to draw one conclusion regarding a range. It is an improper question.

THE COURT: Okay. I'll sustain that. You can back that up, Mr. Slonim, or split them up, I guess, whatever you want to do.

Q (By Mr. Slonim) Do you agree with me that the Hattenhauer paper finds an incidence of 10.2 per hundred thousand?

Are you in Exhibit 4?
A Yes, sir. I'm just looking for the exact number.
Q Your -- take a look at the abstract, or if you want to look at the whole document, I don't have a problem. Take a look at the abstract --
A Yes, sir.

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Q -- under the results. The annual incidence -- the crude annual incidence was 10.3 per hundred thousand individuals, correct?
A 10.3, yes, sir.
Q And then it says when adjusted for age and sex distribution of the 1990 white population, the incidence was 10.2 per hundred thousand, correct?
A Yes, sir.
Q Okay. And then take a look, please, at the Johnson and Arnold paper. You can take a look at the abstract for this purpose, I think.
It says that among subjects who were 50 or older the estimated mean annual incidence rates per hundred thousand population were 2.3 for nonarteritic anterior ischemic optic neuropathy, correct?
A That is correct, yes, sir.
Q Okay. And so when you use the range of 2.3 per hundred thousand to 10.2 per hundred thousand, that's what generates the number of 1500 to 6,000 cases per year, correct?
A I believe that is correct.
Q Okay. And that's the figure that you report in Exhibit 3 in the first paragraph

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and the same data that you cite, correct?
A That is correct.
Q Okay. Now, Dr. McGwin, you're familiar with the term "risk factors"?
A Yes, sir.
Q What are risk factors?
A Risk factors are characteristics -- genetic, demographic, medical -- that predispose or perhaps reduce one's predilection for certain diseases.
Q Okay. And diseases that affect the cardiovascular system such as diabetes, high blood pressure and high cholesterol, those are risk factors for erectile dysfunction, correct?
A They are hypothesized risk factors.
Q Have you seen any data, have you looked for any data or studies that weigh in that question?
A Personally?
Q Yes.
A No, sir.
Q You cited the Gorkin paper, correct?
A In our BJO article.
Q You cited it in your expert report in this matter, correct?

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A I would have to refer to the report to verify that.
Q You know the Pfizer paper reporting on clinical trial studies?
A I'm not familiar with it, sir.
(Deposition Exhibit Number 8 was marked for identification.)
Q We've marked as Deposition Exhibit Number 8 your report in this matter; is that correct?
A Yes, sir.
Q Turn, please, to page 4. On the bottom of page 4 you refer to a Pfizer published manuscript, correct?
A That is correct.
Q Okay. And let's mark as Deposition Exhibit Number 9 a paper by Gorkin and others entitled "Sildenafil citrate use and the incidence of nonarteritic anterior ischemic optic neuropathy."
(Deposition Exhibit Number 9 was marked for identification.)
Q This is the Pfizer manuscript that you referenced in your expert report that reports on the 103 clinical studies, correct?

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A That is correct.
Q Okay. And take a look, please, on Exhibit 9. That's the Gorkin paper, first page -- that's page number 500, I guess, in the journal article -- on the right-hand side at the full paragraph that begins with, "Many of the risk factors" -- it says, "Many of the risk factors for developing NAION also predict the occurrence of erectile dysfunction (ED), such as hypertension, diabetes, hyperlipidemia and smoking," and they cite references 7 through 9, correct?
A That is correct.
Q Okay. Now, the same diseases that are risk factors for erectile dysfunction are also risk factors for NAION, correct?
A Can the question be read again?
Q Yes.
A I'm sorry.
Q I'll repeat it. That's fine. I want to make sure you have the question clearly in mind before you answer.
The same diseases -- hypertension, diabetes, high cholesterol -- are also risk factors -- that are risk factors for ED are also

risk factors for NAION, correct?
A Yes.
Q In other words, just so it's clear, Dr. McGwin, conditions, cardiovascular conditions such as diabetes, high blood pressure, and high cholesterol, they are risk factors for both erectile dysfunction and for NAION, correct?
A That is correct.
Q And because men who are at an elevated risk of developing -- strike that.
Let's mark as the next deposition exhibit -- Dr. McGwin, yeah, we -- I guess we skipped a number in the exhibit marking. We've marked -- we marked the Gorkin article as Exhibit 9. We marked your report as Exhibit 8, so we skipped the 7. I'm going to --
MR. OVERHOLTZ: 7 was the report?
MR. SLONIM: No. 8 was the report.
MR. OVERHOLTZ: Oh, okay.
MR. SLONIM: 9 was the Gorkin article.
MR. OVERHOLTZ: I've got you.
(Deposition Exhibit Number 7 was marked for identification.)

Q I'm going to mark as Deposition Exhibit Number 7 an article by Salomon and others entitled "Analysis of Prothrombotic and Vascular Risk Factors in Patients with Nonarteritic Anterior Ischemic Optic Neuropathy."
Is this a paper that you've come across in any of your work?
A I don't immediately recognize it, but that's not to say that I haven't read it before.
Q Okay. Dr. McGwin, I'm going to ask you some questions about this paper and some of the findings. Let's do this: Take a couple of minutes right now, read the abstract, read particularly Table 2. I'm not going to ask a whole lot of questions; but if you need to read the whole paper, we'll take a break and we'll have you read the whole paper. But take a minute right now and familiarize yourself with it a little bit.
A The abstract and table?
Q The abstract and then Table 2 and the discussion around Table 2.
A Can I write on this?

Q Sure. Okay.
A Thank you.
Q And, Dr. McGwin, if you need more time, we will give it to you. The objective of this study was to analyze whether blood clotting disorders or certain vascular diseases played a role in causing NAION or its recurrence, correct?
A I believe that is correct.
Q Okay. And among the conditions they looked at was ischemic heart disease, correct?
A Conditions they looked at as risk factors?
Q Yes. One of the conditions they looked at was a condition called ischemic heart disease, correct?
A Yes, sir.
Q Okay. And what they found in this particular study was that men that had ischemic heart disease were 2.9 times more likely to develop than men that did not have ischemic heart disease, correct?
A My -- can you point to specifically where that number comes from in the paper?
Q Yeah. It appears in the discussion

of Table 2. If you take a look -- take a look at page 740, please, the right-hand side. The last sentence, the authors say, referring to Table 2, "Statistically significant differences were observed between patients and controlled subjects with respect to ischemic heart disease, hypercholesterolemia, and diabetes mellitus with univariate odds of 2.9," and then they give the confidence interval, 2.6 and the confidence interval, and 2.3 and they give a confidence interval, correct?
A That is correct.
Q Okay. And so in this particular study, at least, the authors found that men who had ischemic heart disease were 2. times (sic) more likely to develop NAION than men that did not have ischemic heart disease, correct?
A 2. how many times?
Q 2.9?
A Well, their later adjusted analysis -- it may be a minor point -- suggests that the association for ischemic heart disease is 2.8, so -- adjusted for the effects of the other characteristics.
Q Okay. So the rate -- when they did

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an -- the unadjusted odds ratio was 2.9 and then the adjusted odds ratio was 2.8?
A Yes, sir.
Q But in any event, they found, then, a statistically significant increased risk of men that had a history of ischemic heart disease having NAION in the order of 2.8 or 2.9?
A Yes, sir.
Q Okay. And likewise, they found that high cholesterol -- strike that.
These authors also found that men who had high cholesterol were approximately 2.6 times more likely to develop NAION than men who did not have high cholesterol, correct?
A If you are referring to the univariate results on page 740, that is correct.
Q Okay. And those same studies also indicated that men who had diabetes were about 2.3 times more likely to develop NAION than men who did not have diabetes, correct?
A Again, if you are referring to the univariate results on 740, that is correct.
Q Okay.
A On page 740.
Q Okay. And men who have ischemic

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heart disease and who have high cholesterol and who have diabetes, they are also -- those are cardiovascular conditions that are associated with erectile dysfunction, correct?
A Diabetes isn't a cardiovascular condition, per se.
Q Let me rephrase the question. Men who have high cholesterol, who have ischemic heart disease and have diabetes are also at an increased risk of developing erectile dysfunction, correct?
A There are studies suggesting that, yes, sir.
Q Okay. And because men who have erectile dysfunction are the men who are likely to take an erectile dysfunction medication like Viagra, it's not at all surprising that some of these men are going to have NAION because they have an elevated risk for developing NAION, correct?
A Could you say that again, please?
Q Yes. Men who have ischemic heart disease, who have high cholesterol, and who have diabetes are at an elevated risk for developing NAION and are also at an elevated risk for

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developing erectile dysfunction, correct?
MR. BECNEL: Objection, compound.
THE COURT: Overruled. You can answer it.
A I'm sorry, could you state --
Q Yes, yes.
THE COURT: Let's stop here for a second. Let's get Mr. Becnel on the record, folks, so you know who you've got here.
MR. SLONIM: Do you want to identify yourself?
MR. BECNEL: Daniel Becnel.
Q (By Mr. Slonim) Okay. Let's -- let me rephrase the question.
A I'm sorry. I apologize.
Q No. Let me -- let me rephrase the question.
In the Gorkin article that we discussed a few minutes ago, we saw that conditions such as hypertension, diabetes, and hyperlipidemia were risk factors for erectile dysfunction, correct?
A Have been shown in other articles to be risk factors.
Q Yes. And in the Salomon study that

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we have marked as Deposition Exhibit Number 7, these authors find that men who have ischemic heart disease, men who have high cholesterol, and men who have diabetes are at an elevated risk of developing NAION ranging from 2.3 to 2.8 or 2.9, correct?
A That is correct.
Q Okay. And of course it's the men who have risk factors for erectile dysfunction, that's the population of men who are likely to take Viagra, correct?
A I would think so, yes, sir.
Q Okay. Given the background incidence of NAION among the population of men who have risk factors for erectile dysfunction, a man who took a Viagra and subsequently was diagnosed with NAION might have developed NAION even if he had never taken Viagra, correct?
MR. OVERHOLTZ: Object to the form. Calls for speculation.
THE COURT: Overruled. You may answer it, Doctor.
MR. OVERHOLTZ: I'm just going to restate the objection. My objection is that he is asking a medical diagnosis question here of a

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nonphysician. We've already established he's not a physician who makes diagnoses of NAION. I mean, if he wants to ask him epidemiology questions about whether or not a person who took a Viagra had an increased risk, then I think that's an appropriate question.

THE COURT: He can ask him the question; and if he can answer it, he can answer it. If he can't, he can't. It's overruled.

MR. OVERHOLTZ: Okay.

MR. SLONIM: May I rephrase -- repeat the question so the witness has it in mind?

THE COURT: Yes.

Q (By Mr. Slonim) Dr. McGwin, given the background incidence of NAION in the population of men who have risk factors for erectile dysfunction -- do you have that premise?

A Can we stop there for one second?

Q Yes.

A Do we know what the background incidence of NAION is in that population?

Q We know what the background incidence of NAION is, and we know that men who

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have -- we know that men who have ischemic heart disease, high cholesterol, and diabetes, according to the Salomon article, have more than a twofold increase in risk, correct?

A Yes, sir, but that doesn't necessarily give me a now background incidence number to work from.

Q Here's the question. See if you can answer it.

A Okay.

Q Given the background incidence of NAION in the population of men who have risk factors for erectile dysfunction, a man who took Viagra and then subsequently was diagnosed with NAION might have developed NAION even if he had not taken Viagra, correct?

A I think it's virtually impossible to answer that question as to what caused the disease in that particular individual. I mean, as an epidemiologist, I can speak to what happens in populations and what studies say put people at increased risk, but I --

Q Okay. Have you, Dr. McGwin, looked at the incidence of NAION in the population of people with erectile dysfunction?

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A No, sir.

Q What are case reports and case series?

A Case reports are generally medical publications describing an individual case, usually something unusual, an unusual medical procedure, an unusual disease. Oftentimes they are used to identify hypotheses about these unusual cases -- individual cases.

Case series are simply aggregates of those individual case reports, at least two people, usually more than that, often demonstrating, again, unusual medical procedures or, perhaps, unusual combinations of hypothesized risk factors in groups of individuals.

Q There have been case reports and case series indicating that some men who took Viagra were subsequently diagnosed with NAION, correct?

A Yes, sir.

Q Okay. Let's refer to your own article which we've marked as Deposition Exhibit Number -- bear with me while I find it.

A I think it's Number 3.

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Q Hang on to that. Hang on to your copy. Here's my copy. Thanks.

Okay. Take a look, please, at Deposition Exhibit Number 3, your article, the lower left-hand side, the paragraph that begins with the word "unfortunately." You wrote, "To date, there is no empirical evidence for or against an association between sildenafil or tadalafil and NAION. The only published studies have been case reports and case series, which by their nature, do not provide a comparison group." That's what you wrote, correct?

A That is what I wrote, yes, sir.

Q Okay. And your point here is that case reports and case series because they lack a comparison group cannot scientifically test whether men who take Viagra are at an increased risk of developing NAION as compared with men of the same age and medical condition not taking Viagra, correct?

A That's correct.

MR. OVERHOLTZ: Objection. Objection. It misstates the quote. The witness can answer. You can answer.

A Sorry.

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Q The men -- the men in the case reports and case series where there were reports of someone taking Viagra and then subsequently coming down with NAION, those men might have developed NAION even if they had never taken a Viagra, correct?
A I don't feel qualified to say what those men might or might not have done.
Q Okay.
(Discussion off the record.)
Q Dr. McGwin, if you want to scientifically test the hypothesis that use of Viagra can cause NAION, you must utilize comparative scientific studies. You can't simply rely on case reports and case series, correct?
A That is correct.
Q Okay. And in your expert report in this matter -- we marked that as Deposition Exhibit Number 8 -- turn to page 3. In about the middle of the page you wrote that in the field of epidemiology, there is a hierarchy in evidence and that -- and then now I begin the quote, "At the bottom of this hierarchy are case reports and case series reflecting their

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inability to test scientific hypotheses," correct?
A Yes, sir.
Q Okay. And your point here is that because case reports and case series have no comparison group, they cannot be used scientifically to test the hypothesis such as the hypothesis that the use of Viagra can cause NAION, correct?
A That is correct.
Q Okay.
MR. SLONIM: Judge Borg, we've been going for a little bit less than an hour. We could take a break now, or I'm happy to plod on.
THE COURT: Sure. No, I'll leave that to you.
VIDEOGRAPHER: We have 16 minutes left on this tape.
THE COURT: 16. Yeah, let's take that, do it.
MR. SLONIM: We can take just a short break, and then we will move on.
THE COURT: Okay.
MR. SLONIM: Thanks.
VIDEOGRAPHER: The time is 8:57, and

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we're off the record.
(Recess taken.)
VIDEOGRAPHER: The time is 9:09. This is the beginning of Tape Number 2. We are back on record.
Q (By Mr. Slonim) Dr. McGwin, are you familiar with a type of epidemiological study called a case-control study?
A Yes, sir.
Q Okay. Let's mark as Deposition Exhibit Number 10 a diagram of a case-control study.
(Deposition Exhibit Number 10 was marked for identification.)
Q Can you identify that as a schematic or a diagram of a case-control study?
A Yes, sir.
Q And in a case-control study, Dr. McGwin, an investigator starts with a group of people who have a certain disease, and those are called the cases, and then selects a group of individuals who do not have the disease who are called the controls; is that right?
A That is correct. Although, there are variants where one might start with a cohort

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and select a case and control group from that.
Q Okay. So what we -- take a look at Exhibit 10. It's divided into the two halves, the cases and the controls, correct?
A Yes, sir.
Q Okay. And then what the researcher does is compares the two groups in terms of whether they were exposed to the substance that is suspected of being associated with the disease, correct?
A Substance or disease, other disease, risk factor, et cetera, yes, sir.
Q Okay. And if the substance is associated with or causes the disease, you would expect a higher proportion of the cases to have been exposed to the substance than the controls, correct?
A I agree with the use of the word "associated with," but causes is not what case-control studies or epidemiological studies demonstrate.
Q What's the -- explain that, please.
A Well, epidemiology is able to demonstrate associations, not identify causes of diseases.

Q Okay.
A So when you said that -- I don't remember the exact --
Q Let me rephrase the question.
A Okay.
Q Thank you. So when the investigator who is conducting the case-control study compares the two groups, if the substance that's being investigated is associated with the disease, you would expect a higher proportion of the cases to have been exposed to the substance than the controls, correct?
A If it is a positive association, yes.
Q Okay. And we have previously marked, Dr. McGwin, your study of nonarteritic anterior ischemic optic neuropathy and erectile dysfunction medications as Exhibit 3. Can you put that in front of you?
A Uh-huh.
Q The style of that study, the study design is a case-control study, correct?
A Specifically, yes, a matched case-control study.
Q Okay. And just for clarification,

tell us what you mean by the word "matched."
A In case-control studies, generally they are as you described: One selects a group of cases, and one selects a group of controls who don't have the disease of interest. Oftentimes there are what are known as confounding characteristics. These are, I'll use the word, generically ancillary characteristics that we know are associated with the disease and with the exposure of interest but aren't risk factors in the context of the study. And one can remove the effect, the statistical effect of those third, sort of, factors by matching the case and the control group on most frequently age, gender, and race so that any impact of age is removed, any impact of race is removed. And what one ends up with is a group of cases and controls that are similar in those characteristics.
Q And so when you designed your case-control study, you took that extra step of doing the matching in an effort to try to minimize or eliminate the effect of possible disparities along those lines of possible confounders?

A Yes, sir.
Q Okay. The medications that you studied in this article were Viagra and also another medication for erectile dysfunction called Cialis, correct?
A That is correct.
Q Okay. I want to walk through some of the steps of the study with you. How were the cases selected?
A The cases were selected from the University of Alabama at Birmingham Department of Ophthalmology Clinic. There are -- at the time we did this study, there were two neuro-ophthalmologists practicing in the clinic, and neuro-ophthalmologists are individuals who would generally treat in patients with NAION. And we reviewed retrospectively the medical records of these two practicing physicians to obtain the cases for this particular study.
And if I can just go back for a minute, when I say we reviewed the medical records, we first obtained from the hospital -- I believe it's data resources, but I'll -- the data resources office a printout of ICD-9 codes for this particular disease and then we --

Q Let's go back a little bit. The first thing that you did, as I understand it, based on your description of methods is that you got a printout of ICD-9-CM Code 377.41, correct?
A The first thing we did is get a printout of all the ICD-9 codes for all the patients seen. And then from that list we selected.
Q Code Number 377.41?
A Yes, sir.
Q Okay. And that is a code that's used basically to classify cases so you can retrieve them that decodes to ischemic optic neuropathy, correct?
A That is correct.
Q And then after you -- after you got -- so you started off you got all cases of optic disorders, and then you looked at the subset of Code Number 377.41, correct?
A We got all cases of patients seen, not just those with optic disorders.
Q All cases seen. And then you looked at the subset that were coded to 377.41, correct?
A That is correct.

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Q Okay. And then you went, as I understood it, and pulled medical record abstracts; is that right?
A We pulled the medical records and then abstracted them.
Q You went and pulled the medical records for those patients and you abstracted them?
A Yes, sir.
Q Okay. Why did you do that?
A They are -- the ICD-9 code that we referred to, 377.41, or any ICD-9 code that is in an administrative data system may be incorrect -- a key stroke error when it's being entered following the initial patient visit. There are a number of reasons why those, you know, codes may be in error; and therefore, we wanted to be certain that the patients that we identified as having that code did in fact have a clinical diagnosis of NAION.
Q And in fact, 370 -- Code Number 377.41 is ischemic optic neuropathy. It is not limited to nonarteritic anterior ischemic optic neuropathy, correct?
A That is correct.

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Q So even on its face, that code is not capturing -- even if all the data entry was perfect, that code would not be capturing precisely the cases that you were looking to investigate, correct?
A That is correct.
Q So even if there's no data entry, you would have to do some kind of review to weed out the cases that you were not interested in?
A That is correct. And can I --
Q Please.
A In consultation with Dr. Vaphiades, the second author, Michael Vaphiades, and the chair of ophthalmology, Dr. Lanning Kline, who is a neuro-ophthalmologist, when we selected that particular code they informed us that when they see patients with NAION, this is the code that they use. And as you indicated, it is a generic code, but it was the code that started us off for the group of patients that we knew that would subsequently by medical record have this condition.
Q So in other words, if you had simply relied on Code Number 377.41 without going through these extra steps of analyzing the

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medical records and abstracting them, the cases would have been misclassified?
A There was certainly the potential for that.
Q Okay. In how many instances did you find a case that was coded to 377.41 where the medical record failed to confirm NAION?
A I don't believe there was any that -- to my recollection all of the cases that were identified with that code were then subsequently confirmed by medical record review as NAION.
Q Okay.
A I would have to go back to our data abstractions and verify that, but to my recollection.
Q But in any event, in order to make sure that there were -- that you were capturing the right cases medically and to make sure that somewhere a computer operator doing the coding somewhere along the way didn't make an error, you did not simply rely on the case code, you took the extra step of going and actually analyzing the medical records in consultation with doctors, specialists in ophthalmology and

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neuro-ophthalmology to make sure that the cases that you identified were really the cases that you were interested in which were NAION; is that right?
A That is correct.
Q Okay. How were the controls selected?
A As I referred to previously, we obtained not just a list of 377.41, we obtained a listing of all the patients seen in the time period of interest, January 2002 to February 2004. So we had people who were being seen for just refraction, people who were being seen for glaucoma, macular degeneration, a variety of problems. Basically, anyone who came to that clinic during that time in addition to the NAION cases were in this file. And we selected the controls, people who didn't have NAION, randomly from the remainder of that list.
And also as I described previously, this was a match study, so we were looking for people who -- if we had a case who was a, for example, 50-year-old African-American male, we would go and identify at random one 50-year-old African-American male as that person's matched

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control.
Q Who didn't have NAION, had some other disorder?
A That's correct. That's correct.
Q Were female cases and controls selected?
A As part of the larger study, female cases and controls were selected.
Q Just one clarification. When you said that you matched on race, take a look, please, at the bottom of page 154.
A I apologize. I misspoke.
Q The cases and controls were matched on the basis of two variables, age and sex, correct?
A Yes.
Q And the age match was not an exact birth date, plus or minus a --
A Plus or minus.
Q Plus or minus a year, correct?
A Yes, sir.
Q Okay. So the two variables in which you matched?
A I'm sorry. I apologize. I was wrapped up in my example and I --

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Q Okay. Okay. And you got cases of NAION by going through this procedure where you started off with the ICD codes, went to the medical records, you got your cases. You got your -- you got your controls from the listing of people that were at the clinic, not NAION cases, and then you did -- and then you matched them on the basis of sex and age and that was the basis for the cases and controls --
A Yes, sir.
Q -- right?
Okay. And let me just go back. I want to -- bear with me for a second.
Now, you said that female cases and controls were selected, correct?
A Yes, sir.
Q Okay. How many cases and controls were female?
A Can I look at something in this binder?
Q Sure. Is it in the article?
A In the article that is marked Exhibit 3 --
Q Yes.
A -- we limited this particular study

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to males.
Q Okay.
A There was a -- this article here was actually part of a larger study on risk factors for NAION. When we designed this particular analysis being interested in Viagra, we limited this analysis, this publication to males. There is, in fact, a larger study that underlies this that does in fact include females.
Q And has that resulted in a publication?
A There is another publication which has presently been accepted for publication and is available on the British Journal of Ophthalmology Web site. And I have a copy of the manuscript here, and I can read the title if --
Q Sure.
A -- that would be helpful.
Q Yes.
A "Nonarteritic Anterior Ischemic Optic Neuropathy and Presumed Sleep Apnea Syndrome Screened by the Sleep Apnea Scale of the Sleep Disorders Questionnaire."
Do you want me to read the authors?

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Q Sure.
A Okay. The first author, who at the time was a Ph.D. student in the department of epidemiology, is Jian Li. The second author is myself, Gerald McGwin, Jr. The third author is Dr. Michael S. Vaphiades, and the senior author is Dr. Cynthia Owsley.
Q And as I understand, this manuscript has been accepted and is actually available to the public online?
A That is correct. The British Journal of Ophthalmology has a procedure or policy wherein recently accepted articles, although not appearing in the print version of the journal, are available on their Web site.
Q So when the study was originally designed, conceived and designed, what was the purpose?
A The original purpose of the -- let me backtrack. Dr. Michael Vaphiades is a neuro-ophthalmologist, and he and I speak frequently about epidemiology and eye disease. And he had made some observations that there have been several publications recently on hypothesized risk factors for NAION, NAION,

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several of which you mentioned, your case series and the case reports that we discussed. And he thought it would be interesting to pursue an epidemiologic study wherein we looked at some of these risk factors, we formally tested some of these hypotheses.

He to my recollection made the comment that there hadn't been a lot of what we refer to as etiologic studies in this condition because it was rare and also just generally there aren't a lot of epidemiologists interested in eye disease. You put that combination together, and you don't get a lot of literature.

And so I subsequently talked with my colleagues and we decided to do a study wherein we looked at a broad array of risk factors. And at the time, if one looked at the literature, one would have found several of the case reports that you mentioned on Viagra. Several -- you would have also found a recently published paper, although the exact manuscript escapes me, on sleep apnea, that patients had been observed with NAION also having sleep apnea.

And in speaking with Dr. Vaphiades and, again, reading the literature, much of

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which we have referred to in here, one would also find certain medical conditions -- diabetes, several of the ones that you mentioned -- as hypothesized risk factors. And as is fairly common in epidemiology, one could view, again, the larger study, not Exhibit 3, the larger study that we were conducting as an exploratory study wherein a number of risk factors are evaluated.

MR. BECNEL: Counsel, can we attach a copy of that article as an exhibit to the deposition and get it photocopied later?

MR. SLONIM: You will get your chance.

Q Dr. McGwin, turn, please, to Table 1 of Exhibit 3. This table, this nine categories of demographic and medical characteristics, that reports the number of cases and controls that had each of those characteristics, correct?

A Yes, sir.

Q Okay. I wanted to ask some questions about some of these.

A There's some writing on here that's not mine. Is that -- is that not good?

MS. LESKIN: You gave him your copy.

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MR. SLONIM: Yep.

THE WITNESS: I'm sorry, I read it.

MR. BECNEL: Now I want to enter it.

THE WITNESS: I'm sorry, I read what it said.

MR. BECNEL: Did he admit liability or not?

THE WITNESS: I have my own copy, if that's --

MR. SLONIM: No, that's okay.

THE WITNESS: I'm sorry.

MR. SLONIM: No problem.

MS. LESKIN: Do you want this one?

Q (By Mr. Slonim) Let's make sure I understand some of these. Let's start with alcohol. First of all, you had 38 cases and 38 controls, correct, in your study?

A In the final analysis, yes, sir, 38 cases and 38 controls.

Q Okay. And one of the things that you asked each of the people that participated about was their use of alcohol; is that right?

A That is correct.

Q And what you found was that actually 29 of the cases acknowledged alcohol use and 29

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of the controls acknowledged alcohol use, right?

A Yes, sir.

Q Okay. And you get a p-value there of .99. What does the p-value mean?

A The p-value is the -- what's referred to as the statistical significance of that comparison, of 29 cases and 29 controls or probably more appropriately the 76.3 percent and the 76.3 percent. It is a measure of probability that the observed differences -- here there's no difference -- but that the observed differences are due to chance and that the p-value is a measure of that probability.

Q And the fact that the p-value is .99 indicates what in regard to whether or not this is a result of chance?

A Did you say what?

Q Yes.

A The conventional criteria for there being a difference, a statistically significant difference is a p-value of .05. And p-values that are less than .05 are generally accepted as being statistically significant differences.

In this particular case here, the p-value of .99 means that there's no

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statistically significant difference. In fact, you can tell by the exact same numbers that they are exactly the same.
Q Okay. Take a look at another one, myocardial infarction. And by the way, just for the record, myocardial infarction is a medical term, and a layperson would refer to that as a heart attack, correct?
A I believe that is correct.
Q Okay. And in there what you found in your cases, that 52.6 percent of the cases had a history of myocardial infarction as compared with 26.3 percent of the controls, correct?
A That is what we found, yes, sir.
Q Okay. And you got a p-value there of 0.02, correct?
A Yes, sir.
Q Which is less than the 0.05, correct?
A That is correct.
Q Tell me what the p-value of .02 means in the myocardial infarction characteristic.
A With respect to the results from

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myocardial infarction, it means that the cases have a statistically significantly higher frequency of myocardial infarction compared to the controls.
Q And that means that that difference is unlikely to be due to chance; is that correct?
A That is correct.
Q Go ahead, please.
A Unlikely, but we've attached an actual quantitative estimate to that. We've said that the probability is .02 or fairly small, yes.
Q So the probability -- the probability that that difference is due to chance would be two percent?
A That is correct.
Q Okay. And then take a look at the diabetes characteristic, or I should say medical condition. What you found as I understand Table 1 is that for cases, 26.3 percent of those cases had diabetes whereas 34.2 percent of the controls had a history of diabetes, correct?
A Yes, sir.
Q Okay. And there you find -- so they

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were -- the cases had -- the percentage of cases that had diabetes was lower than the percentage of controls that had diabetes, correct?
A That is correct. The absolute frequency was in fact lower.
Q Okay. And you get a p-value of .45; is that right?
A Yes, sir.
Q And give us the interpretation of that p-value then. It is not statistically significant, correct?
A Can I do the interpretation and then --
Q Please, please.
A Okay. If we sort of keep using this cut-point of alpha .05, we would conclude that those differences that we observed there are not in fact -- and I'll put this in quotes -- "real," that although the frequency of diabetes is lower in the cases, that that difference could easily be due to chance. And the .45, again, provides us a quantitative estimate. It doesn't meet our alpha -- our .05 cut-point.
Q In other words, if you pulled this sample at random from a broader population,

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there's a 45 percent probability that you would have gotten this distribution purely as a result of the play of chance or purely as the result of chance alone, correct?
A If we pulled this repeatedly there would be a 45 percent chance -- no, I would not agree with that.
Q How would you phrase it?
A I guess -- how would I phrase it? I would say that you are -- right church, wrong pew.
Q Okay.
A With respect to -- the p-value refers to the data as it has been collected, not necessarily to future collections of similar data. I'm not sure if that makes sense. Your statement connotes that we could take this p-value here and sort of use it as a benchmark for future sampling.
Q Okay.
A Whereas the p-value really is specific to the data as it has been collected.
Q Okay. So in other words, given the fact -- given your 38 cases and controls, the probability that this observed difference with

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respect to diabetes occurred purely as a result of chance is 45 percent; is that right?
A That's more correct, yes, sir.
Q Okay. Now, just looking at the risk factors -- or strike that.
Just looking at the medical characteristics of coronary artery disease, myocardial infarction, high cholesterol, and hypertension, in other words, the bottom four --
A Yes, sir.
Q -- a higher percentage of cases than controls had those conditions, correct?
A That is correct.
Q Although the only one that's statistically significant is the myocardial infarction?
A That is correct. If we use the conventional .05 cut-point, which we did in this paper.
Q Okay. Now, those conditions -- hypertension, coronary artery disease, myocardial infarction, and high cholesterol -- are also conditions that predispose people to erectile dysfunction, correct?
A Yes, sir.

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Q Okay. So because more of your cases or a higher percentage of your cases had those four conditions -- the hypertension, the coronary artery disease, the myocardial infarction, and the high cholesterol -- than controls, you would expect a higher percentage of use of Viagra among the cases than controls because those people were predisposed to ED, correct?
MR. OVERHOLTZ: Object to the form. It calls for speculation. I don't know that there is a foundational way that he could even answer that question.
MS. LESKIN: Judge.
THE COURT: I'm sorry. Overruled. You can answer the question. If he's able.
A Yes, I would agree.
Q Okay. And in fact, I mean, one of the reasons I understood that you did adjusting, the matching and adjusting was to try to equalize for those potential differences; is that right?
A Well, we matched on the demographic characteristics.
Q Yeah.

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A And the adjustment -- that's exactly right. That was -- the attempt was to remove the dependence of those conditions.
Q Okay. I want to turn next -- I think I understand Table 1. I want to turn next to Table 2.
Again, you indicate in this table that there were 38 cases and 38 controls, correct?
A That is correct.
Q Okay. And of your 38 cases, how many were exposed to Viagra?
A It looks to be 14 in here.
Q Okay. And that would mean that 24 were not exposed to Viagra?
A That's correct.
Q Okay. And of your 38 controls, how many were exposed to Viagra?
A That's interesting. This actually says 14 but the percentage is off. Table 2 says that there are 14.
Q Okay. Now, and then how many were not exposed to Viagra?
A If the paper says that there are 14, then there would be a subsequent 28 that would

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not have been.
Q 24?
A Yes, sorry. 24, yes, sir.
Q Now, if the data is that 14 cases were exposed to Viagra and 14 controls were exposed to Viagra as reported in Table 2, the odds ratio would be 1.0, wouldn't it?
A I would have to do the calculations, but it would be my guess that it would be, yes, sir.
Q Well, it's not a guess. It's the exact same number were exposed, the exact same percentages, correct?
A That is correct.
Q So there's something wrong with Table 2, right?
A Yes, I would agree with you there is something wrong with Table 2.
Q Either the percentage is wrong or the number of people that were exposed is wrong, correct?
A That is correct.
Q Mathematically, those numbers are all inconsistent -- are inconsistent with each other in Line 1 of Viagra use; isn't that right?

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A Could you restate the --
Q Yes, let me rephrase that. If the numbers of people exposed to Viagra in cases and controls was 14 as set forth in Table 2, the odds ratio would be .1 -- would be 1.0, correct?
A Yes.
Q Okay. But you are reporting an odds ratio, an unadjusted adds ratio of 1.25, correct?
A An unadjusted odds ratio, yes, sir.
Q So something is wrong with Table 2, right?
A Yes. My suspicion is is that the number is wrong.
Q Which number?
A Oh, pardon me. Under the controls in Table 2, the 14 Viagra users.
Q Okay. And if that was 12, would the numbers work?
A I would have to have a calculator, but --
Q If you divide 12 into 38, you have 31.6 -- I mean, the other way around. If you divide 38 into 12, you get 31.6?
A Are you telling me or asking me?

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Q I'm asking you.
A If I had a calculator, I could --
MR. OVERHOLTZ: Do you want to give him a calculator?
MR. SLONIM: I actually don't have one.
THE WITNESS: I have one in my phone but I turned it off because --
MR. SLONIM: Do you have a calculator?
THE WITNESS: I mean, on these computers there should all be little calculators. I'm not very good with numbers. I'm sorry.
Q (By Mr. Slonim) I think if you use the number 12, it will come out to 31.6.
A Actually it is not --
Q It's not?
A It's not working. I mean -- pardon me. It's -- I am not referring to the calculation. I can't get the --
Q Let's do this. Let's not digress. We will come back to it.
A If one divides 12 by 38, the result is in fact 31.58 which if one rounds up is 31.6.

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Q Okay. And then the rest of the numbers would be consistent, correct?
A That is correct.
Q Okay.
A Thank you.
Q Now, let's go over to the next -- go over two columns to the odds ratio, please.
A The adjusted or the --
Q Let's start with the unadjusted --
A Yes, sir.
Q The 1.25?
A Yes, sir.
Q Tell us what that odds ratio means.
A Sure. Would it be useful if I provided some context for the odds ratio itself?
Q Sure, sure.
A In a case-control study, the common measure of association is an odds ratio, and the odds ratio measures -- it's a ratio of probability. So that's just a ratio of odds, which is -- and odds is a probability. And so in this particular case, what we are calculating is the odds of exposure among the cases compared to the odds of exposure among the controls. And

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here the calculation of odds is taken as the probability of the exposure over one minus that probability. And then those are taken as odds. So the odds ratio measures for us the association between the exposure and the disease in this case.
So if we would translate into English that 1.25, one can say that the cases were 1.25 times or 25 percent more likely to have reported using Viagra compared to the controls.
Q Okay. Good. I'm sorry, I didn't mean to --
A It is frequently the approach for calculating odds ratios, one can do it by hand, one could use a statistical technique called logistic regression to do it, which I would be happy to go into painful detail to describe.
The matched nature of this study means that there are specific statistics for matched studies, and we used a conditional, which is regression. The word "conditional" refers to the fact that the study, the design of this study has to take into account the matching that we report.

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Q Okay. So if I just put it in a simple two-by-two table using the 14 and 24 for the cases and the 12 and the 26 for the controls, I wouldn't quite reproduce your probability, your odds ratio?
A That's right. For matched studies, if I can provide more detail, the traditional two-by-two table which in the columns have cases and controls and in the rows have exposed and unexposed, that is not the appropriate presentation for a matched study.
What one presents in a matched study is the matched pairs, the discordant pairs and then the concordant pairs.
Q Understood.
A So the two-by-two table is correct, but the organization of the data for a matched study is different.
Q Understood. Now, your next column is the adjusted odds ratio, correct?
A Yes, sir.
Q Okay. And referring to the first line on the Viagra use you get an adjusted odds ratio of 1.75, correct?
A That is correct.

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Q And tell us what the difference is between the adjusted and the unadjusted odds ratio.
A Okay. As we looked at in Table 1, there are a number of characteristics that albeit not statistically significant, there are differences between the cases and the controls. There's only one myocardial infarction, which was statistically significant.
The case control design, in fact most epidemiologic designs, are observational studies. What this means is that while often there's a primary characteristic of interest, in this case Viagra, there are other what are known as confounding factors that need to be accounted for. That is, there are things between the cases and the controls that are different.
When one -- it is often referred to as adjusting for them. I don't particularly care for that term because it connotes a sense of control that one doesn't truly have. When we adjust for these characteristics, we attempt to statistically remove those differences so that one is -- what one is left with is a -- pure is a strong word, but an independent effect that is

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free of those differences that you attempted to adjust.
Q So in other words, when you looked at Table 1, you identified demographic and medical characteristics that were -- that were potentially different between cases and controls and you report that data in Table 1, right?
A Yes, sir.
Q And then in Table 2 in the right-hand column in the adjusted odds ratio, what you attempt to do is to do a statistical adjustment on the data to make it as if there were no differences between the cases and controls on those nine variables in Table 1; is that right?
A To say that we make so that there are no differences is not a hundred percent correct.
Q Okay.
A What we are attempting to do is minimize those differences on that association of interest.
Q Okay. And did you -- when you made your adjustment, did you try to adjust for all nine variables that you identified in Table 1?

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A Did we try to, or did we?
Q Did you?
A The only thing that wouldn't have been included in that particular statistical model would have been age.
Q Okay. So you adjusted for eight variables?
A According to the table, we adjusted for all variables in Table 1 except age.
Q It's a footnote, I guess, that I didn't refer to. I apologize.
Given that there were eight variables that you were adjusting for in a population of 38 cases and 38 controls, was there any concern about the statistical ability to do that calculation?
A There is -- there is a rule of thumb that goes -- it is a ten-for-one rule. For every independent variable included in a statistical model, and here independent variable meaning a risk factor, one should have ten events or cases. And the one-for-ten rule would apply to a cohort study, clinical trial, whatever the case may be. So in this case, ten cases.

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There's recent evidence in the epidemiologic and statistical literature that that one-for-ten rule is a vast overestimate.
So to answer your question, I would say while the rule of thumb suggests that we did not have enough cases to support that number of variables in the model, it is an issue that is not without controversy.
Q Okay. So some people would accept it and some people would not accept it as a reliable statistical adjustment when you have eight variables for which you are controlling and 38 cases?
A That is correct. Some people wouldn't; some people would.
Q Your p-value here is .64, is that correct, for Viagra?
A Oh, yes, sir.
Q And we've all -- the whole discussion has been on Line 1 of the table. It's the Viagra line, just so it's clear. The p-value here is .64, correct?
A Yes, sir.
Q Now, does that .64 apply to the unadjusted odds ratio, the adjusted odds ratio

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or both? What does it apply to?
A While I can't state with a certainty, it is my practice to have it refer to the unadjusted result.
Q Okay. And the odds ratio that you observed, the .125 (sic) which is the unadjusted and the 1.75 which is the adjusted, that odds ratio is not statistically significant, correct?
A The 1.75 would not be statistically significant.
Q And nor would the 1.25?
A Nor would the 1.25, no, sir.
Q And in fact, the p-value here -- that's shown by the p-value of .64, correct?
A Yes, sir.
Q And the p-value of .64 means that there's a 64 percent probability that the odds ratio that you observed is the result of chance, correct?
A That would be one interpretation of it, yes, sir.
Q Another way of phrasing this, a p-value of 64 means that there is a 64 percent probability that the odds ratio was the result of random noise in the data, correct?

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A Random noise could be one potential explanation, yes, sir.
Q Let's turn next to Table 3, please. Now this table presents data for men who used Viagra and/or Cialis and who had a history of either heart attack or high blood pressure compared with men who used neither medication and had no history of either heart attack or high blood pressure; is that right?
A Yes, sir.
Q Now, you don't indicate here whether the odds ratios that you are reporting were adjusted or unadjusted. Can you tell us which they were?
A These would be adjusted.
Q What technique did you use to do the adjustment?
A Conditional logistic regression. Can I clarify?
Q Please.
A Conditional logistic regression would be the statistical model that one used. The statistical model is based on more complicated statistics, maximum likelihood estimates. So I guess depending on how specific

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you want to be.
Conditional logistic regression is the statistical tool. There are some arithmetic, some fairly complicated statistics that are used by the logistic regression model.
Q Did you adjust in Table 3 for all of the demographic factors reflected in Table 1?
A I can't state it with a certainty. I believe that was the case save age.
Q Age. Is there any reason why you didn't -- in Table 2 you reported the adjusted and the unadjusted. Here you didn't indicate. Is there any reason why you didn't report the unadjusted?
A I believe it was due to space.
Q Okay. The Table 3, this presents no data for men who used Viagra alone compared with men who did not use Viagra; is that right?
A That is correct.
Q And in this article when you report the odds ratio, you did not report the odds ratio for men who used Viagra alone and had a history of myocardial infarction, correct?
A Oh, you mean in the text of the article?

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Q No. I'm talking about Table 3.
A Viagra -- no, sir.
Q And likewise in your article on Table 3, you did not report the odds ratio for men who used Viagra alone and had a history of hypertension, correct?
A No, sir.
Q Now, take a look, please, at your expert report that we marked previously. I think it is Exhibit Number 3.
MS. LESKIN: 8.
Q 8, I'm sorry. Do you have your expert report in front of you?
A Yes, sir.
Q Turn to page 2, please. In this paragraph, last paragraph on the bottom of the page in about the middle of the paragraph you are reporting about the McGwin study, the study that we've just been discussing, correct?
A Yes, sir.
Q Okay. And with regard to this Table 3, in your expert report what you state referring to your article is that the authors also reported an odds ratio of 10.7 for men who used Viagra. Let's stop right there. Oh, and

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had a history of myocardial infarction.
A The sentence that begins, "The authors also reported" --
Q Yes.
A Yes, sir.
Q I want to focus just on -- let's read it so it's just clear.
The authors also reported an OR, odds ratio, of 10.7 for men who reported Viagra use and a history of myocardial infarction.
Stop right there. That's what you wrote in your expert report, correct?
A That is in fact what I wrote.
Q Okay. And contrary to what that sentence says or that portion of the sentence says, in your article you report no odds ratio data for men who reported Viagra use alone and had a history of myocardial infarction, correct?
A That's correct, yeah.
Q So that sentence is wrong?
A Yes, that's correct.
Q And by the same token, that sentence where you say "and an odds ratio for men who reported Viagra use and a history of hypertension" -- I'm sorry. Let me rephrase

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that. I misspoke.
You also said that the -- that your -- in your expert report, you also said that your article reported an odds ratio of 6.9 for men who reported Viagra use and a history of hypertension when in fact your article does not report any data for men who used Viagra alone and had a history of hypertension, correct?
A That's correct.
Q Okay. So that entire sentence is not reported by your article, correct?
A That's correct.
Q Turn to your article, please, page 156.
A Okay.
Q Do you see the subheading on the left-hand side that says "Discussion"?
A Yes, sir.
Q Okay. And on the left-hand side, you wrote that you observed, and I quote, that you "observed a positive yet not statistically significant associations between Viagra and/or Cialis and the occurrence of NAION," correct?
A That is correct.
Q And you used the phrase "not

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statistically significant" to acknowledge the fact that your study results could be attributable to chance, correct?
A That is correct.
Q And then on that same paragraph going down to the bottom, the last sentence on that same paragraph under "Discussion" --
A Yes, sir. Yes, sir.
Q Okay. You wrote that the lack of precision associated with these estimates provides little evidence regarding the true strength of association should it truly exist.
You used the phrase "should it truly exist" to acknowledge the fact that your study did not prove that Viagra could cause NAION, correct?
A Could you restate the question?
Q Yes. You used the phrase "should it truly exist" to indicate and acknowledge that your study did not prove that Viagra could cause NAION, correct?
A The objective of the study was not to prove that Viagra caused NAION, so I doubt I would have written a sentence towards that end.
Q Let me rephrase it. You used the

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phrase "should it truly exist" to indicate that the associations that you reported were not proven by your study, correct?
A The phrase "should it truly exist" acknowledges the fact that there is no one study that is going to provide evidence of causation. The phrase "should it truly exist" reflects the current literature with some individuals suggesting there is a relationship and as we've seen others suggesting that there is no relationship so that the phrase "should it truly exist" really reflects the fact that it's an epidemiologic study attempting to quantify an association.
The leading part of the sentence that you read bespeaks the fact that it was a small and a sample size with wide, 95 percent confidence intervals and that the true estimate, should there be one, if we could actually know the truth, was difficult to find in this context.
Q Okay. Your study does not establish that a true association exists. That's why you used the word "should it truly exist," correct?
A Our study did not establish an

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association between Viagra and NAION overall.
Q Okay. On the same page on the lower right-hand portion of the page, the last paragraph, you were -- do you see that, the paragraph --
A The one that begins with the Food and Drug --
Q The Food and Drug Administration. You wrote that the Food and Drug Administration has issued a statement regarding reports of patients experiencing a sudden loss of vision attributed to NAION after taking Viagra, Cialis and Levitra. This statement is clear that no link has been established between these medications and the occurrence of NAION.
That's what you wrote, correct?
A That is what I wrote, yes, sir.
Q Okay. And you give a reference for that statement, that FDA statement as Reference Number 17; is that right?
A Yes, it is Reference Number 17.
MR. SLONIM: Let's mark that one as an exhibit.
(Deposition Exhibit Number 11 was marked for identification.)

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A Thank you.
Q Is that Exhibit 11?
A Yes, it is. I'm sorry. I'm just trying to get these in order.
Q We've marked as Deposition Exhibit Number 11 an FDA press release, FDA statement issued July 8th, 2005. Do you have that in front of you?
A Yes, sir.
Q Okay. And that's the -- that is Reference Number 17 cited in your published article, correct?
A It is, yes, sir.
Q And referring then to the third paragraph of the FDA statement, the FDA states, and I quote, "It is not possible to determine whether these oral medications for erectile dysfunction were the cause of the loss of eyesight or whether the problem is related to other factors such as high blood pressure or diabetes or to a combination of these problems," correct?
MR. OVERHOLTZ: I'm going to object to the form. It leaves out the beginning of that sentence by the FDA.

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MR. SLONIM: I'll read the whole thing.
Q Dr. McGwin, let me rephrase the question to address the objection.
The third paragraph of Exhibit Number 11, which is the FDA statement that you cite in your article, says, "At this time, it is not possible to determine whether these oral medications for erectile dysfunction were the cause of the loss of eyesight or whether the problem is related to other factors such as high blood pressure or diabetes or to a combination of these problems," correct?
A Yes, sir.
Q Okay. And your purpose in telling your readers in your article that the FDA had made this statement was to make sure that you had called to the attention of readers the fact that the FDA was unable to conclude that Viagra could cause NAION, correct?
A That's correct.
Q Okay. Counsel pointed out correctly that this statement that we've marked as Deposition Exhibit 11 is dated July 8th, 2005, and it indicates "at this time."

Let's mark as Deposition Exhibit Number 12 a document I printed from the FDA Web site within the last few days.

(Defendant's Exhibit Number 12 was marked for identification.)

VIDEOGRAPHER: Mr. Slonim, we have five minutes on the tape.

MR. SLONIM: Okay.

Q This is the FDA Patient Information Sheet currently on the FDA Web site that we've marked as Deposition Exhibit Number 12. Do you see in the top left the FDA alert is dated July 2005?

A Yes, sir.

Q Okay. In the second paragraph of the alert, the FDA says, "We do not know at this time if Viagra, Cialis or Levitra causes NAION," correct?

A It does say that, yes, sir.

Q And that's the same thing that the FDA said in Exhibit Number 11 that was issued on July 8th, 2005, correct?

A The sentence is not the same, but the --

Q The thrust?

A Yeah, is the same.

Q Okay. And then take a look at the italics on the bottom of the first page. It says that this information reflects FDA's current analysis of data available to FDA concerning this drug. FDA intends to update this sheet when additional information or analyses become available, correct?

A Correct.

Q And you notice that this document was printed on June 11th, 2007? Do you see that on the footer?

A Yes, sir.

Q Okay. To your knowledge, the FDA has not come out with any different statement about Viagra and NAION, correct?

A To my knowledge -- I haven't checked.

Q You are not aware of any contrary statement by the FDA?

A No.

Q Okay.

MS. SLONIM: Do you need to change the tape?

VIDEOGRAPHER: We have three

minutes.

MR. SLONIM: Sure.

VIDEOGRAPHER: The time is 10:07. This concludes Tape Number 2. We are off the record.

(Recess taken.)

VIDEOGRAPHER: The time is 10:27. This is the beginning of Tape Number 3. We are back on the record.

Q (By Mr. Slonim) Okay. Let's mark as Deposition Exhibit Number 3 (sic) an article by Fraunfelder, Pomeranz, and Egan. It is actually an editorial entitled "Nonarteritic Anterior Ischemic Optic Neuropathy and Sildenafil."

(Deposition Exhibit Number 13 was marked for identification.)

Q Dr. McGwin, I should have asked this earlier. A couple of times we've used the term, you or I have used the term "sildenafil." You understand that that is the chemical name for Viagra. Viagra is the brand name or the trade name?

A That is my understanding, yes, sir.

Q Good. You understand that Dr. Pomeranz who is one of the coauthors on this

piece is also an expert for plaintiffs in this matter?

A Yes, that is my understanding.

Q Okay. And have you seen this Exhibit Number 13 previously?

A Yes, sir.

Q Okay. And take a look, please, at the right-hand side slightly above the middle, the first full paragraph. Dr. Pomeranz and his coauthors write that a well-researched explanation as to how sildenafil therapy could cause NAION does not exist, correct? That's what they wrote?

A The complete sentence begins with "despite the above," but yes, that's correct.

Q And in the preceding paragraph, they refer to different hypotheses that have been suggested about -- that could possibly link Viagra to NAION; is that right?

A That's correct.

Q Okay. They talk, for instance, about a possible hypotensive effect in Dr. Hayreh's hypothesis, correct?

A That's correct.

Q And then they go on in the paragraph

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on the right, the first full paragraph, and they say, "Despite those hypotheses above, a well-researched explanation as to how sildenafil therapy could cause NAION does not exist," correct?
A Yes, sir.
Q Okay. And in fact, as we noticed earlier in the article that you coauthored, I think we marked it as Exhibit Number 2 with Dr. Girkin, that paper says that there is no good experimental model of NAION, correct?
A That's correct.
Q Okay. And then referring back to this Exhibit Number 13, the piece that was written by Dr. Pomeranz and coauthors, they write in the second full paragraph on the right-hand side that until an animal model or scientific study reveals a biological basis for NAION caused by treatment with sildenafil, most of the case reports of NAION related to this drug may be an expected coincidence as sildenafil is a top-selling medication and patients who receive this drug are frequently older, vasculopathic, and already at risk for NAION, correct?

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A That is correct. That's what it says.
Q Okay. And you agree that the reports of NAION among men who have used Viagra could be a coincidence, correct?
A Yes, I would agree with that.
Q In other words, it could be the fact that these men were at risk for developing NAION and this just could be a coincidental finding?
A That's correct.
Q Okay. Now, Dr. McGwin, one of the papers that you cited in your expert report in this matter was a paper by authors Margo and French. Do you recall that?
A My citation or the paper itself?
Q Do you recall the paper?
A Yes, sir.
Q Okay. And you did cite it, correct?
A I don't know the exact location, but it's likely that I did as I was aware of it at the time I wrote that report.
(Deposition Exhibit Number 14 was marked for identification.)
A Thank you.
Q We've marked as Deposition Exhibit

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Number 14 a publication by authors Margo and French entitled "Ischemic Optic Neuropathy in Male Veterans Prescribed Phosphodiesterase Inhibitors." Do you have that in front of you?
A Yes, sir.
Q And this is a paper that you've read previously, correct?
A Yes, sir.
Q And in fact, you referenced this in your expert report, correct?
A Yes, sir.
Q Okay. Now, Margo and French in this paper did not conduct either a cohort study or case-control study; is that right?
A They refer to it as a retrospective cohort study.
Q Well, isn't what they did an exploratory study to determine whether or not it would be feasible to control -- to conduct a case-control study?
A Could you say that question again?
Q Yes. Take a look at the -- the purpose of the study was to determine the feasibility of a case-control study of PDE5 inhibitors and NAION, correct?

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A That is the stated purpose, yes, sir.
Q And what this was was an exploratory study to determine whether or not it would be feasible to conduct a case-control study; isn't that right?
A I don't believe they ever call it an exploratory study. Are you asking about the study design itself?
Q Yes, yes.
A The study design per their own words is a retrospective cohort study.
Q Does it meet your -- as a professor of epidemiology, does it meet your criteria for what you would call a retrospective cohort study?
A Yes, sir, it does.
Q Okay. Now, Margo and French attempted to identify cases of NAION, and they refer to it as "NION," by using these ICD-9-CM codes, correct?
A That is correct.
Q Okay. And you and I previously talked about that in connection with your own study, correct?

A Yes, sir.
Q And Margo and French, in fact, used ICD-9-CM Code 377.41, correct?
A That is correct.
Q And that code does not distinguish between arteritic and nonarteritic forms of ischemic optic neuropathy, correct?
A No, sir. It refers to ischemic optic neuropathy.
Q Okay. So it could be either arteritic or nonarteritic, correct?
A That's correct.
Q And so what they did was they tried without looking at medical records to pull out the cases that might be arteritic, correct? They identified cases that responded to ICD-9-CM codes and then they excluded cases where there was either temporal arteritis or something like that, correct?
A That would be my interpretation of what they did, yes, sir.
Q The ICD-9-CM Code 377.41 also does not distinguish between ischemic optic neuropathy that occurs in the anterior portion of the optic nerve and optic neuropathy that

occurs in other portions of the optic nerve, correct?
A Not to my knowledge.
Q Okay. And Margo and French did not review the medical records or interview patients in an effort to confirm that the cases that they thought were NAION were actually really NAION; is that right?
A That's -- that's correct.
Q Okay. So the method that Margo and French used to identify cases of NAION was susceptible to case misclassification, correct?
A That's correct.
Q And, in fact, they own up to that. They write in their paper, they acknowledge that a weakness of their study was the failure to analyze medical records to confirm the presence of NAION, correct? It is on the bottom -- it is on page 539, bottom left.
A Yes, sir.
Q Okay. They also define cases of possible NAION, correct?
A Yes, sir.
Q And possible NAION they define as cases of papillitis or optic neuritis, correct?

A Yes, sir.
Q Okay. And so that's even a broader definition -- the definition of possible NAION is even a broader definition than the definition that they had previously used of NAION and in that respect is even more prone to misclassification of cases --
MR. OVERHOLTZ: Object to form. Lack of foundation.
Q -- correct?
THE COURT: Overruled. You may answer the question.
A The question is is it more subject to misclassification?
Q Yes. Let me rephrase it. In the definition of -- let me withdraw it and rephrase it.
In the definition of possible NAION, Margo and French are affirmatively including cases that are not classified as even ischemic optic neuropathy, correct?
A Yes, sir.
Q So they are affirmatively including cases that are coded to things other than ischemic optic neuropathy, correct?

A That is correct.
Q But if the subject matter that they are interested in is NAION, they are going to be pulling in cases that are non-NAION cases when they use this definition of possible NAION, correct?
A Yes. Yes, sir.
Q And so in that respect, it's prone to misclassification of cases, correct?
A Yes, sir.
Q Okay. Now, referring to their definition of NION, Margo and French found that men who used a PDE5 inhibitor, not just Viagra but a PDE5 inhibitor, did not have a statistically significant increased risk of NAION as compared with nonusers, correct?
A They do not provide the p-value for the association that you are referring to, but one could infer from the confidence interval that it would not be statistically significant.
Q Okay. And just so it is clear on the record, you are looking now on page 539 at the bottom left-hand side where Margo and French write that the relative risk of NION for men prescribed PDE inhibitors was 1.02 per a 95

percent confidence interval, 0.92 to 1.12, correct?
A That is what I'm referring to, yes, sir.
Q Okay. And so first of all, the relative risk that they report is just barely above 1.0, correct?
A Yes, sir.
Q Okay. And if it was 1.0, regardless of statistical significance, that would be no increased relative risk?
A No difference, that's correct.
Q So this is just barely above -- two-hundredths of a -- two-hundredths above no increased risk, correct?
A That's correct.
Q But even that bare elevation is not statistically significant as shown by the fact that the 95 percent confidence interval crosses 1.0, correct?
A That's correct; although, I -- can I clarify that statement?
Q Sure.
A It is often -- 95 percent confidence intervals are often used as indicators of

statistical significance. And it is probably -- well, it may not be important to you, but it is important to point out that there can be confidence intervals that include the null value yet are statistically significant because the manner in which confidence intervals and p-values are calculated are in fact different. I just want to point that out.
Q Okay. Normally epidemiologists feel that when a 95 percent confidence interval includes 1, the result is not statistically significant, correct?
A I can't speak to what most epidemiologists would normally do. Myself, I would refer to the p-value itself if I was interested in statistical significance. One does not perform statistical significance testing using confidence intervals.
Q Okay. In any event, you don't have any reason based on the data that's provided to think that this 1.02 relative risk is statistically significant, do you?
A No, sir.
Q Okay. Margo and French did find a statistically significant increased risk of

possible NAION, correct?
A That is correct.
Q Okay. And let's read the sentence. The RR, or relative risk, of possible NION for men prescribed a PDE5 inhibitor was 1.34 percent, 95 percent confidence interval, 1.17 to 1.55, correct?
A That is correct.
Q Okay. And as we -- you and I discussed a minute ago, possible NAION is not NAION by definition, correct?
A That's correct.
Q Okay. And in fact, referring to that particular finding looking to the right-hand side of the page, Margo and French say that the increased risk of papillitis-optic neuritis observed in men prescribed PDE5 inhibitors in this study is difficult to explain in this age group and deserves further investigation, correct?
A They do say that, that's correct.
Q Now, looking at this page 539 on the lower left-hand side, Margo and French acknowledge that their study has certain weaknesses, correct?

A Yes, sir, they do.
Q And specifically they acknowledge that they did not in the course of doing this work verify the accuracy of the diagnostic codes that they relied on, correct?
A Yes, sir.
Q And what that means is that cases that they treated as if they were NAION in reality might not have even been NAION, correct?
A Yes, sir.
Q Okay. And they also acknowledge that they did not know the temporal relationship between the use of a PDE5 inhibitor and the diagnosis of NAION, correct?
A Yes, sir.
Q In other words, in the work that Margo and French did, they could have counted as cases of NAION instances where a person developed NAION before he ever took a PDE5 inhibitor, correct?
A Yes, that's certainly possible.
Q Okay. Obviously if a person developed NAION before he was ever exposed to a PDE5 inhibitor, the medication could not have caused the NAION, correct?

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A Yes, that's correct.
Q You agree with me that a cause must precede an effect?
A That's correct.
Q At least in our world.
The Margo and French study does not conclude that men who take Viagra are at a statistically significant increased risk of developing NAION compared with nonusers, correct?
A Could you say that –
Q Yeah, yeah. The Margo and French study does not reach the conclusion that men who take Viagra are at a statistically significant increased risk of developing NAION compared with nonusers, correct?
A That's correct.
Q Okay. Now, turn back to page 538 of this paper, please. And I'll direct your attention towards the bottom of that page and then it's going to continue on to the next page. Margo and French write, and I quote, "Because PDE5 inhibitors are targeted to men who have vasculopathic factors, it is also possible that any association is coincidental. To date,

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there is no definitive evidence to support a causal relationship," correct?
A That is in fact what they said, yes, sir.
Q Okay. And that is precisely what the Food and Drug Administration wrote in the two documents that we identified as exhibits earlier that at this time it is not known if Viagra, Cialis or Levitra causes NAION, correct?
A That is correct.
Q And that is the same thing that Fraunfelder and Pomeranz and Egan wrote in the document we just marked as an exhibit where they say it could be a coincidence, correct? That's Exhibit 13.
A That's correct.
Q Okay. Are you familiar with a type of study called a randomized clinical study?
A Yes, sir.
Q And what is that?
A Randomized clinical study are often a -- also referred to as a randomized clinical trial. It's a study design wherein as opposed to being observational, the risk factor, the exposure of interest is randomly assigned.

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There are variants of this study design in terms of how the randomization is done and the specific types of study design, the crossover study, et cetera.
But, generally, it departs from epidemiology in that it's not observational.
Q It is experimental?
A It is in fact experimental, yes, sir.
Q And in terms of the hierarchy of epidemiological evidence, where does the randomized clinical study stand in comparison to a case-control study?
A Relative to a case-control study, it is higher.
Q And where does it stand relative to case reports or case theories?
A Oh, it is much higher.
Q Okay. And in the case of Viagra, you know that there have been randomized clinical studies of the medication, correct?
A Yes, sir.
Q Let's take a look at the Gorkin paper that we previously marked as a deposition exhibit. Let's see if I can find it.

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A I believe it is 9.
Q 9?
A Yes, sir. I have an extra --
Q I've gotten my papers out of order.
A I have an extra copy, if you want.
Q That's okay. Turn, please, to page 502. I'll direct your attention to the left-hand side. And in part on the left-hand side this article discusses 103 double-blind or open-label clinical studies of Viagra, correct?
A Yes, sir.
Q Okay. And in those 103 studies, there were more than 13,400 men who participated in the studies, correct?
A That is what it says, yes, sir.
Q Okay. And these more than 13,400 men were followed on average for approximately one year, correct?
A It does not say that, but one could infer that from the number of patient years that are stated here.
Q The studies include 13,400 men, more than that, and approximately 13,300 patient years of observation, correct?
A Yes, sir.

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Q So that's pretty clear that on average that the follow-up for each patient was approximately one year --
A Yes, sir.
Q -- correct?
Okay. And in those 103 clinical studies involving more than 13,400 men, there were no cases of NAION that were reported, correct?
A That's correct.
Q Okay. And then the article goes on to discuss the International Men's Health Study, correct?
A Yes, it does.
Q And the International Men's Health Study was designed as a prospective cohort study, correct?
A Yes, sir.
Q And what's the difference between a prospective cohort study and a randomized clinical trial?
A They -- what's the difference or how --
Q Yes, what is the difference?
A The assignment of the treatment, the

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exposure, the medication, whatever the risk factor of interest is.
Q Okay. And how is it different?
A In a prospective cohort study, it is again observational. One simply ascertains what the normal behaviors of the individual are. And in the clinical trial, as we discussed, you, the investigator, randomly assigns who receives that particular risk factor or in this case medication.
Q But it has the virtue of being prospective, even though the assignment is not random?
A That's correct, yes, sir.
Q So it doesn't have whatever problems may be introduced by trying to go backward in time and get people's recollections?
A That's correct.
Q And in the International Men's Health Study, there were 3,812 men that participated in the study, correct?
A Yes, sir.
Q And they were followed on average of slightly less than one year, correct?
A Yes, sir.

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Q Okay. And there were no reported cases of NAION among those 3,812 men in the International Men's Health Study, correct?
A That's correct.
Q Okay. And then the article describes a third study that was conducted, the prescription event monitoring study in the United Kingdom, correct?
A Yes, sir.
Q And that study was designed as a retrospective cohort study, correct?
A Although it doesn't state it, I know that that is how it was designed.
Q You are familiar with PEM studies?
A Yes, sir.
Q Okay. And you know that they are retrospective cohort? What is the difference between a retrospective cohort study and a prospective cohort study?
A The main difference is where the investigator, the person doing the study is standing at the time both the exposure and the outcomes have occurred.
Q Okay.
A And in a prospective study, the

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investigator is standing at the beginning. The events haven't occurred yet, although the exposures might have. In a retrospective study, generally both the exposures and the events have already happened. And often these are secondary analyses of existing data that are used for these retrospective studies.
Q Okay. And in the prescription event monitoring study involving Viagra, there were more than 28,000 men who were studied, correct? Do you see there were two phases? There was --
A Oh, 22,473 and then 56 -- yes, sir.
Q Okay. And that they were -- these 28,000 men were followed on average for more than one year, correct?
A That is correct.
Q And you know that because for the 28,000 men, approximately, that were in the study, the study reported approximately 35,500 patient years of observation, correct?
A Yes, sir.
Q And that indicates that each man was followed on average for more than a year?
A Yes, sir.
Q Okay. And there was one reported

case of NAION among those 35,500 patient years of observation, correct?
A That is correct.
Q Okay. And one case of NAION in 35,500 patient years of observation means that the incidence of NAION in this cohort is 2.8 per hundred thousand patient years, correct?
MR. OVERHOLTZ: I object to form. It misstates the statements in the report that this was patient years of observation as opposed to patient years of using Viagra.
THE COURT: Overruled. You may answer the question.
A The manuscript does in fact state that the unadjusted incidence was 2.8 per hundred thousand person years.
Q Okay. And based on the Johnson and Arnold and Hattenhauer studies that you and I looked at at the beginning of this deposition, the background incidence of NAION in the population of men over age 50 ranges from about 2.3 to 10.3 per hundred thousand per year, correct?
A I would -- no, I would not agree with that.

Q Let's take a look at the ION decompression trial paper that we marked as Exhibit Number 6.
A Newman?
Q Yes, the Newman paper.
A Yes, sir.
Q This was one of the exhibits that you cited in your report on Viagra and NAION, correct?
A I believe that is correct.
Q This is a paper you referenced. Okay. And in the first paragraph of Exhibit 6, the ION decompression trial study, the author states that the annual incidence of NAION has been estimated from 2.3 to 10.2 per hundred thousand for persons 50 years and older, correct?
A That is in fact what they state.
Q Okay. And they cite references 3 and 4, which are the Johnson and Arnold and Hattenhauer papers, correct?
A Yes, sir.
Q Based on the Johnson and Arnold and Hattenhauer studies, the background incidence of NAION in the population of men over age 50

ranges from 2.3 to 10.2 per hundred thousand per year, correct?
A Well, each of those studies provides an individual estimate, one of which is 2.3. The other is 10.2.
Q And that gives you a range, correct?
A No. In fact it provides you two numbers. It's important to remember that the rate of 2.3 has its own confidence interval associated with it. And the rate of 10.2 has its on confidence interval associated with it. So what -- the numbers that are being cited are rates from two individual studies, both of which are measured with error.
Q In your article, Dr. McGwin, that was marked as Deposition Exhibit Number 3, you in fact wrote that the range of estimated number of people that are going to get NAION in the United States is from 1500 to 6,000 people per year, correct?
A That is correct.
Q And you base that on that range of 1500 to 6,000 on the Johnson and Arnold and Hattenhauer papers, correct?
A Yes, sir.

Q Okay. And that range from Johnson and Arnold and Hattenhauer is 2.3 to 10.2 per hundred thousand per year, correct?
A Those two studies, as I mentioned, provide two individual estimates. To refer to what is a range fails to acknowledge that they are both measured with a certain degree of error.
Q Bearing that in mind, it is a fact that in Exhibit 3, your article on Viagra, you reported that as the range of new cases in the United States, 1500 to 6,000, correct?
MR. OVERHOLTZ: Object to form. Are we talking about that he reported the 1500 to 6,000 or the 2.3 to 10.2 incidence rates? I just don't want to confuse those two on the record as to what you are asking.
THE COURT: I can barely hear you, Mr. Overholtz, so I'm kind of waiting here to read it.
Are you able to answer the question, Doctor?
THE WITNESS: I can answer the question with respect to what I said in my paper, yes, sir.

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THE COURT: Okay. Go ahead and answer it. It is overruled.
A That is in fact what I state in the paper, yes, sir.
Q (By Mr. Slonim) Okay. In other words, Dr. McGwin, there were no reported cases of NAION among the 13,400 men in the clinical studies. There were no reported cases of men among the 3800 men that participated in the International Men's Health Study --
MR. BECNEL: You misspoke, Counsel. You might want to read it. You used "men" twice.
MR. SLONIM: Let me withdraw the question and I'll rephrase it.
Q Dr. McGwin, referring to the Gorkin paper, there were no reported cases of NAION among the 13,400 men in the clinical studies, there were no reported cases of NAION among the 3800 men in the International Men's Health Study, and one reported case of NAION in the prescription event monitoring study which -- and that one case results in an incidence which is at the lower end of the estimated background incidence of NAION among men over age 50,

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correct?
MR. OVERHOLTZ: Object to the form. Compound question. I mean, it is asking about number of cases per people in a study and then asking whether or not there is a rate regarding compared estimated backgrounds. I'm not sure which question he's answering here.
THE COURT: Overruled. He can answer the question if he's able.
A Can I restate the question?
THE COURT: I was going to say, if he can remember it.
Q Sure, sure.
A I understand the point that you're trying to make, and I guess I'm just trying to acknowledge the fact that there is this background incidence, and I don't argue that if we use the term generically that we have these studies that provide us -- I'm not going to use the word "range" -- ball park estimates.
Q Okay.
A But my concern is that we're failing to recognize that each of those numbers is measured with variability.
Q Fine.

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A And in the lower -- or I can't remember the phrase that you used -- the lower estimate or the -- let me see if I can find it -- the 2.8 number is the estimate from a single study that has its own lower bound to it.
Q Okay.
A So if we're sort of looking at this as combining those two studies, the Hattenhauer study and the Johnson --
Q -- and Arnold --
A -- study, to combine them, we'd be better off taking the data from them, putting the data together, coming up with a single estimate, and getting a confidence interval on it.
So I guess I'm struggling with your question. We're trying to -- you're clearly trying to sort of lay a foundation that these two numbers represent a range of background incidence when in fact the epidemiology suggests that there is some variability that I don't think we are accounting for.
Q Okay.
A I don't know if I'm making myself clear.

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Q Let me try to rephrase it a little bit. Of the two studies that report on background incidence of NAION in the population of the United States, the one paper reports a background incidence of about 10.2 and the other paper reports an annual incidence of about 2.3 per hundred thousand for persons age 50 and older, correct?
A Yeah. Although, the numbers reported in the paper we're taking about, Gorkin, are actually different from that, but those are numbers that are cited in those papers, yes, sir.
Q Okay. Very close?
A Uh-huh, yes, sir.
Q In any event, in the Gorkin paper, there were no cases of NAION in the -- among the 13,000 men in the clinical studies, correct?
A Yes, sir.
Q And there were no cases of NAION among the 3800 --
VIDEOGRAPHER: Mr. Slonim, your paper is rubbing your microphone.
MR. SLONIM: Sorry.
VIDEOGRAPHER: Thank you.

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Q (By Mr. Slonim) And there were no cases of NAION among the -- reported among the 3800 men in the International Men's Health Study, correct?
A That's correct.
Q Okay. So those are both zero. And then we get to the prescription event monitoring study in which there was one case reported of NAION out of the 35,500 patient years of observation which results -- if you convert that into an incidence, it results in a 2.8 per hundred thousand patient years, correct?
A That's correct.
Q Okay. And, therefore, that is lower than the paper that reports the 10.2 per hundred thousand background incidence, correct?
A Yes. That is lower, yes.
Q And it's very close to the incidence that was reported in the other paper, the 2.3 per hundred thousand for the year of men over age 50, correct?
A It's close and higher.
Q A little bit higher, right?
A Yes, sir.
Q Okay. Take a look, please, at page

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502 of the Gorkin article, the last paragraph.
A Of the discussion?
Q Yes, the last paragraph of the discussion. The authors concluded, and I quote, "Rather than supporting an increased incidence of NAION associated with sildenafil use, this analysis of clinical trial and epidemiological data representing approximately 52,000 patient years of observation indicates that the NAION incidence of men with ED" -- that's erectile dysfunction -- "who took sildenafil worldwide is consistent with the range of estimated NAION incidence in the general U.S. population," correct?
A That is in fact what it says, yes, sir.
Q Okay. And the Gorkin article was published in a peer-reviewed medical journal; is that right?
A I am actually not familiar with this journal.
Q Okay.
(Deposition Exhibit Number 15 was marked for identification.)
Q We've marked as Deposition Exhibit

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Number 15 a page from the Web site of the International Journal of Clinical Practice. Do you have that in front of you?
A Yes, sir.
Q And do you see under Aims and Scope the document states that the IJCP offers rapid, robust peer review and publication, provides the highest standard of author service?
A Yes, sir, it says that.
Q And you don't have any reason to doubt that this International Journal of Clinical Practice is peer reviewed, do you?
A Oh, no.
Q Okay.
A I just wasn't familiar.
Q Okay.
A I hadn't heard of it before.
Q Now, Dr. McGwin, we've talked about three studies. We've talked about your study, we've talked about the Margo and French study, and we've talked about the Gorkin paper, which in turn discusses three studies: the clinical studies, the International Men's Health Study, and the prescription event monitoring study.
It's correct that not a single study

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has found that men who use Viagra have a statistically significant increased risk of NAION, correct?
MR. OVERHOLTZ: Object to the form. I'm just -- I don't know if we are talking about these three studies or if we're talking about all studies. Are we talking about the actual IMH study and PEM study or how Gorkin and those people describe it?
THE COURT: Can you clean that up, Mr. Slonim?
Q (By Mr. Slonim) Dr. McGwin, none of the studies that we've reviewed today -- your study, the Margo and French study, or the Gorkin paper -- find a statistically significant increased risk of NAION among men who use Viagra, correct?
A That is correct.
Q Okay. On the Bradford Hill criteria, which you discuss in your expert report, the first criterion is strength of association, correct?
A Yes, sir.
Q Okay. What is strength of association?

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Let me rephrase it. Dr. McGwin, strength of association refers to the magnitude of the elevated risk, if any, over the background risks, correct?
A Elevated or it could be reduced in certain contexts.
Q Okay. In your own study, Dr. McGwin, you wrote that the lack of precision associated with these estimates provides little evidence regarding the true strength of association should it truly exist, correct?
A I did write that, yes, sir.
Q And none of the other studies that we have discussed have found a statistically significant increased risk of developing NAION among Viagra users, correct?
A Yes, sir.
Q Okay. And you're not aware of any study that we haven't discussed that reports that men who have used Viagra are at a statistically significant increased risk of developing NAION, correct?
A I'm aware of no such studies.
Q In other words, we've covered the universe today?

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A Unless something came out while we were sitting here.
Q Okay. The next criterion under the Bradford Hill set of criteria is called consistency, correct?
A Yes, sir.
Q And consistency refers to the fact that a repeated observation of an association in different studies or in different populations is more indicative of a real association than an isolated study, correct?
A Yes, that is correct.
Q Okay. And in the case of Viagra, as we've discussed, none of the studies have found a statistically significant increased risk of NAION among Viagra users, correct?
A Correct.
Q Okay. The next criterion under the Bradford Hill criteria is specificity, correct?
A That's correct.
Q And specificity refers to the notion of a single -- of a specific exposure being associated with a specific disease, correct?
A Yes, sir.
Q In the case of Viagra and NAION,

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there are millions of men who have taken Viagra without developing NAION, correct?
A I don't know that for a fact, but it would seem reasonable to conclude that.
Q Take a look at the Gorkin paper, page 501.
A Yes, sir.
Q Left-hand side, first full paragraph, the authors report that sildenafil has been approved for the treatment of ED, erectile dysfunction, since 1998 and more than 150 million prescriptions have been written for more than 27 million men worldwide since its approval, correct?
A Yes, sir.
Q Okay. Does that refresh your recollection that in the case of Viagra, millions of men have taken Viagra without developing NAION?
A Yes, sir.
Q And men, as we discussed at the outset of this deposition, were diagnosed with NAION long before Viagra was ever placed on the market in 1998, correct?
A Yes, sir.

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Q Do you agree with me that the specificity criterion is not present here?
A I'm not sure -- you're -- I don't want to put words in your mouth. You are making it seem as if these criteria are fixed, that Hill said that this criteria is met or not and there's no fence-sitting, I guess, so to speak. So when you say that the criteria is not met, I guess I don't see that being in the spirit of how he originally set forth these criteria. In fact, he, himself, doesn't sort of view them in that regard.
Q You wrote in your report, in fact, under the specificity criterion that none of the risk factors associated with NAION have been demonstrated in a conclusive manner, correct?
A Yes, sir.
Q You agree with me that at the very least, you cannot claim based on the state of scientific knowledge currently available that there is a specific association that has been established, correct?
A Can you say that one more time, just that last part?
Q I'm going to withdraw it.

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A Okay.
Q The next criterion is temporal relationship, correct?
A Yes, sir.
Q The idea of a temporal relationship is that if a condition is caused by an exposure to a substance, the exposure must precede the onset of the disease or condition, correct?
A That's correct.
Q Okay. And in the Margo and French study, as you and I discussed, the investigators did not determine whether there was a temporal relationship between the use of Viagra and NAION, correct?
A That was a stated limitation.
Q Yeah. In other words, in the Margo and French study, the patients might have developed NAION before they ever even took Viagra, right?
A Yes, sir.
Q And in your own study, Dr. McGwin, although you tried to ascertain that people -- that the onset of the disease or the condition was after the use of Viagra, you did not obtain information about the exact timing of NAION

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relative to Viagra use, correct?
A Well --
Q Let me withdraw the question. Take a look at your article, please, Exhibit 3, page 156, bottom left. When you talk about the case report, you say, "Many of the existing case reports and series regarding Viagra or Cialis and NAION have been able to isolate the exact timing of use relative to the onset of NAION-associated symptoms. The retrospective nature of the current study makes collecting information with this degree of precision difficult," correct?
A That's correct.
Q Okay. And then you go on further to say that if you wanted to try to ascertain information about the timing, you would need to do another study using a different design such as a case-crossover design, correct?
A Yes, sir.
Q Okay. Have you taken a look at the pharmacokinetic curve of Viagra showing the active ingredient, the concentration of active ingredient in the blood serum per hour?
A I'm going to say no.

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(Deposition Exhibit Number 16 was marked for identification.)
Q We've marked as Deposition Exhibit Number 16 the Viagra label. Over the course of your work, have you had a chance to look at the label for Viagra?
A Yes, sir.
Q Take a look, please, on page 2, Figure 1. This is a plot that shows the concentration of sildenafil, that's Viagra, in the blood plasma starting at the point of ingestion and then following it for 24 hours, correct?
A Yes, sir.
Q Okay. You see at time zero, that's when the person first swallows the pill, the concentration of sildenafil in the blood plasma is zero, correct?
A Yes, sir.
Q And then you see it reaches a maximum concentration in a little bit less than two hours, more like one hour, correct?
A Yes, sir.
Q And then you see that the concentration of sildenafil in the blood plasma

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rapidly begins to fall, correct?
A That is correct.
Q Okay. And then you see that basically after -- 12 hours after ingestion there's very little of the active ingredient in the blood plasma, correct?
A Relative to its peak, yes, sir.
Q And it's sort of an isotopic curve and basically is more -- basically after 12 hours it is pretty well washed out of the system, correct?
A Yes, sir.
Q Okay. So that someone who takes Viagra is under the pharmacological influence of the drug for less than 12 hours, correct?
MR. OVERHOLTZ: I'm just going to object to the form. He's asking him to draw pharmacological conclusions. He stated earlier he wasn't a pharmacologist. If he wants to ask him what does this label report, that's appropriate.
THE COURT: I have to read it. I can't hear you. Overruled. He can answer the question if he's able.
A The figure appears to show that,

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yes, sir.
Q Okay. So in terms of studying whether or not there's a temporal causal relationship with Viagra, understanding the precise timing of when the person took Viagra relative to the onset of NAION is important to understand whether or not there's a temporal relationship between the two, correct?
A Is your question with respect to a study such as a case-control study, or are you using the term when you say "study" more generically -- experimental, animal --
Q Any study.
A I would say the timing is important; although, I'm not certain that the precise timing is as important.
Q If somebody took a Viagra and four days later had NAION based on this pharmacokinetic curve, would you think that there was a reason that Viagra caused the NAION?
A In a given individual?
Q Yes.
A I can't answer that question.
Q In a population?
A Is your question in a study if we

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defined exposure as being limited to -- what did you say?
Q Four days.
A Four days before? That's a difficult question. I would -- I can't remember whether you asked -- if it was affirmative. I will agree with you that that would be difficult. Was that your --
Q Okay. You answered the question.
A Okay.
Q The next criterion is biological gradient, correct?
A Yes, sir.
Q And biological gradient refers to the concept of a dose-response relationship meaning the greater the exposure, the greater the risk of developing the condition, correct?
A Correct.
Q And in the case of Viagra and NAION, there were no studies that report a dose-response relationship, correct?
A That is correct.
Q Okay. And the next criterion under the Bradford Hill criteria is biological plausibility, correct?

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A That is correct.
Q And in your -- the article that you coauthored that we discussed, you indicated that there is no good experimental model of NAION, correct?
A That's correct.
Q Okay. And in the Pomeranz, Fraunfelder, and Egan piece that we marked, they also say that there is no good experimental model of linking Viagra and NAION, correct?
A That's correct.
Q And while there are hypotheses regarding Viagra and NAION, some of which are discussed in the Pomeranz, Fraunfelder, and Egan piece, none of those hypotheses have been tested and proven, correct?
A That's correct.
Q Okay. And in your report, Dr. McGwin, you refer to a hypothesis that Viagra decreases systemic blood pressure which could result in a decreased blood flow to the optic nerve head, correct?
A That is correct.
Q That is one of Dr. Hayreh's hypotheses?

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A Uh-huh.
Q Have you done any research to see whether or not there have been studies that have investigated whether Viagra causes a decreased blood flow to the optic nerve head?
A I have done no such studies.
Q I'll represent to you -- and I'm happy to show it to you, we can take our time -- ten separate studies that have been conducted of Viagra and blood flow to the optic nerve, none of which find a decreased blood flow. Do you want to see those studies?
MR. BECNEL: Objection.
MR. OVERHOLTZ: Argumentative.
MR. BECNEL: That's improper. That's absolutely improper. You know better than that, Counsel.
THE COURT: Just a second, folks. It is overruled. He can answer the question.
A Was the question do I want to see them or --
Q Yeah.
THE COURT: That was the question, do you want to see those studies?
Q Let me withdraw the -- let me

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withdraw the question.
VIDEOGRAPHER: We have five minutes, Mr. Slonim.
MR. SLONIM: I'm sorry?
VIDEOGRAPHER: Five minutes.
MR. SLONIM: Five minutes. Fine.
Q Are you aware of any scientific studies that report that Viagra decreases the flow of blood to the optic nerve head?
A No -- well, am I aware that they exist, or am I familiar enough with the literature to --
Q Are you aware of any study reported in any language in any piece of scientific literature that concludes that Viagra decreases the flow of blood to the optic nerve head?
MR. OVERHOLTZ: I'm going to object to the form of the question with the use of the word "study."
THE COURT: Overruled. You can answer the question, Doctor.
THE WITNESS: Okay.
A I'm not aware of such studies, no, sir.
Q Okay. I'm going to mark ten studies

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as a collective exhibit, and we are going to go through them one at a time and we are going to talk about their conclusions.
MR. BECNEL: Counsel, let's not do it as a collective exhibit. Do them one by one.
THE COURT: Let's see what he's going to do first. Overruled. Go ahead, Mr. Slonim.
Mr. Slonim, is it your intention to mark all ten studies as one exhibit?
MR. SLONIM: I'll do this in a more orderly fashion, Your Honor.
THE COURT: I think it's cleaner for the record.
MR. SLONIM: Yeah.
(Deposition Exhibit Number 17 was marked for identification.)
Q Okay. Dr. McGwin, we've marked as Deposition Exhibit Number 17 an expert report prepared by Dr. Alon Harris, who is an expert who has been consulting with the defendant in this matter. Have you read this report?
A Yes, sir.
Q This was given to you in the course of your work by the plaintiffs, right?

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A Yes, sir.
Q Okay. Let's turn, please, to paragraph -- let me get the right page number. Page 10, Paragraph 16. Dr. Harris writes that ten published peer-reviewed studies have investigated the effect of Viagra on ocular circulation. All ten of the studies contradict or are inconsistent with Hayreh's hypotheses. These studies report either that Viagra has no effect on ocular blood flow, i.e., no decrease, or that it actually increases blood flow, i.e., the opposite of an ischemic effect. None of these studies found, or even suggests, that Viagra decreases ocular circulation or blood flow to the optic nerve head. Hayreh ignores nine of these studies. He disputes the methodology of one of these studies, Grunwald 2001, but his criticism is overstated. See Paragraph 20.
Is that a paragraph that you read when you got this -- when you received Dr. Harris' report?
A Yes, sir.
Q And then in paragraphs 18 through 27, Dr. Harris cites and discusses each one of

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the ten studies, correct?
A Yes, sir.
Q Okay.
MR. SLONIM: The court reporter tells me we need -- the videographer tells me we need to change the tape.
VIDEOGRAPHER: The time is 11:27. This concludes Tape Number 3. We are off the record.
(Recess taken.)
VIDEOGRAPHER: The time is 11:43. This is the beginning of Tape Number 4. We are back on the record.
Q (By Mr. Slonim) Dr. McGwin, we were talking about the Harris report which lists, describes ten studies regarding the effect of Viagra on blood flow to the optic nerve and you had said that you had looked at paragraphs 18 through 27 that discusses each one of those studies in seriatim, correct?
A Yes, sir.
Q Okay. And then on page -- it is actually Paragraph 19 -- I'm sorry, Paragraph 29 on page 19 references a table. And, in fact, each one of the studies is described in a table

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with the results and the conclusions of the studies summarized on the table that appears on pages 19 and 21, correct?
A Yes, sir.
Q Okay. And based on -- did you read any of the -- did you read any of the underlying studies?
A I likely did; although, I don't remember them specifically. The only one that immediately comes to mind is the Grunwald study.
Q There are two Grunwald studies. Do you remember which one?
A No, sir. I'm afraid I do not.
Q In any event, is it your understanding that Dr. Harris in describing these studies purports and quotes language indicating that none of the studies found Viagra to decrease the blood flow to the optic nerve head?
A That is correct.
Q And you are not aware of any studies that find that Viagra decreases the blood flow to the optic nerve head, correct?
A I'm not aware of such studies.
Q Okay. So the bottom line is that

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you're not aware of any studies that support the hypothesis that Viagra decreases blood flow to the optic nerve head, and Dr. Harris cites ten studies that either find an increased flow or no decreased blood flow to the optic nerve, correct?
A Yes and yes.
Q Okay. You also refer to the hypothesis that suggests that vasodilation caused by Viagra could crowd the optic nerve and damage it, correct?
A In my paper or the report?
Q Your report.
A Yes, sir.
Q You're not aware of any study that finds that Viagra has that effect, correct?
A I'm not aware of any such studies, no, sir.
Q In other words, that's an untested and unproven hypothesis?
A Yes, sir.
Q Okay. The next criterion on the Bradford Hill criteria is biological coherence, correct?
A Yes, sir.

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Q This refers to the concept that the positive association -- that a positive association should not conflict with observed scientific facts about the disease, correct?
A Yes, sir.
Q Okay. And you know that the pharmacological effect of Viagra is to cause vasodilatation and a small decrease in blood pressure, correct?
A That is my understanding of how it works, yes, sir.
Q And Dr. Pomeranz in the piece that he wrote with Fraunfelder and Egan that we've marked as Deposition Exhibit 13, those authors comment that even more potent vasodilators than Viagra are not associated with NAION, correct?
A Could you point --
Q Yes. Take a look at the very -- on page 733, the very bottom left-hand side, they talk about the fact --
A Oh, I've got you. Yes, sir.
Q They talk about the fact that Viagra does have a vasodilatory effect and decreases blood pressure. And then they say, "Even potent vasodilators that affect systemic arterial

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circulation are not associated with NAION," correct?
A That is correct.
Q Okay. That fact, the fact that more potent vasodilators than sildenafil are not associated with NAION is inconsistent with the hypothesis that Viagra causes NAION, correct?
A Yes, sir.
Q The next criterion under the Bradford Hill criteria is experimental evidence, correct?
A Yes, sir.
Q And you acknowledge in your expert report that there's no direct experimental evidence regarding the association between Viagra and NAION in the form of human clinical trials or laboratory experiments involving animals, correct?
A Yes, sir.
Q Okay. We already discussed that in the actual clinical studies involving more than 13,300 men that there were no reported cases of NAION, correct?
A Correct.
Q And you also know that in the animal

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toxicology studies, that several different species were administered very large doses of Viagra for extended periods of time and that there was no evidence of injury to the optic nerve, the retina, or any portion of the eye or visual system, correct?
MR. OVERHOLTZ: Object to the form. Lack of foundation.
THE COURT: Overruled. You can answer the question if you're able.
A I'm not familiar with those studies.
Q Yeah, you are. I notice that you brought with you in that collection of documents the Laties-Zrenner article, but I'll mark it separately as an exhibit.
(Deposition Exhibit Number 18 was marked for identification.)
Q We've marked as Deposition Exhibit Number 18 an article by Laties and Zrenner entitled "Viagra (sildenafil citrate) and ophthalmology." This is an article you've seen before, isn't it?
A Yes, sir.
Q Okay. In fact, you brought it with you --

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A Yes, sir.
Q -- in your materials today?
Okay. Turn, please, to page 491 and then we'll to continue on to 492. Page 491 starts talking about the animal toxicology, correct?
A Section 421?
Q Yes.
A Yes, sir.
Q Okay. And turn on to the following page, page 492. Take a minute and read that paragraph up at the top.
MR. OVERHOLTZ: Are you referring to the continuation paragraph?
MR. SLONIM: Yeah.
Q You can start -- it is only two paragraphs. Read the --
A Yeah, I started on the prior --
Q Yeah, read the entire two paragraphs.
A Okay. Got it.
Q This article, this report on pages 491 and 492 reports on the animal toxicology studies involving Viagra, correct?
A Yes, sir.

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Q Okay. And it indicates that several species of animals, dogs and rats, were administered very large doses of Viagra, doses that were 60 to 150 times the human therapeutic equivalent of those, correct?
A Yes, sir.
Q And they were dosed at this very large range, this 60 to 150 times the equivalent human dose for periods of time ranging from 6 to 24 months, correct?
A Yes, sir.
Q And following those studies, the animals were examined and there was found to be no injury to the optic nerve, the retina or any portion of the eye or visual system, correct?
MR. OVERHOLTZ: I object to the form. Compound.
THE COURT: I'm sorry, the objection?
MR. OVERHOLTZ: It is a compound question.
THE COURT: Overruled. You can answer, Doctor, if you are able to do that.
A I see where they mention the retina, but --

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Q Okay. Do you see on the top of page 492, after the authors tell us that the animals were dosed at approximately 60 to 150 times the maximum amount of the human equivalent --
A Yes, sir, uh-huh.
Q -- the next sentence says, "No evidence of histopathological abnormalities in any of the major internal structures of the eyes or the neuronal aspects of the visual pathways was found despite this chronic sustained exposure to excessive free plasma sildenafil concentrations, correct?
A Yes, sir.
Q Okay. And in other words, what they are saying is that there was no evidence of injury to the optic nerve, the retina or any portion of the eye or visual system; isn't that a fact?
A Yes, sir.
Q Now, the next criterion under the Bradford Hill set of criteria is called analogy, correct?
A I believe it is. Let me confirm it. Yes, sir.
Q And analogy refers to a situation

where similar associations have been observed between other exposures and a disease or condition, correct?
A Yes, sir.
Q And in the case of PDE5 inhibitors, the other PDE5 inhibitors, that refers to Cialis and Levitra, correct?
A Yes, sir.
Q As the Food and Drug Administration stated in its press release and its Patient Information Sheet that we previously marked as exhibits, a causal relationship between those agents and NAION has not been demonstrated, correct?
A That's correct.
(Deposition Exhibit Number 19 was marked for identification.)
A Do I get the numbered one or the --
Q Yes, you get the numbered one.
Dr. McGwin, we've marked as Deposition Exhibit Number 19 a subpoena in this action. Have you seen this before?
A Yes, sir.
Q Okay. And this asks you to bring certain documents to the deposition with you.

A Yes, it does.
Q Okay. And I know you showed me before the deposition began that you brought a binder of materials with you?
A Yes.
Q And counsel did send us an e-mail or -- an e-mail that attached a letter stating an objection to Specification Number 18 which asks for underlying data and documents related to your published study. Are you aware of that letter objection?
A Is it a letter that I wrote?
Q No. It is a letter that Mr. Overholtz wrote. Let's do this.
MR. OVERHOLTZ: If you want to show it to him --
Q Let me withdraw this question, and we will mark it as an exhibit.
(Deposition Exhibit Number 20 was marked for identification.)
Q We've marked as Deposition Exhibit Number 20 a letter from Neil Overholtz to Lori Leskin dated June 8th, 2007. Have you seen this before?
A This is the first time I've seen

this letter.
Q Okay. You note -- take a look -- well, take a second to read it.
A I read it. Yeah, I just read it.
Q Okay. In the specification for documents that we have, in Specification 20 we requested underlying documents relating to your study.
MR. OVERHOLTZ: 18, you mean?
Q I'm sorry, I misspoke.
In Specification Number 18 --
A Oh, 18. Sure.
Q -- we requested documents relating to your underlying study. In response to that particular request, Mr. Overholtz sent us the letter that we've marked as Deposition Exhibit Number 20.
Can you tell me what confidentiality agreements are there between the study's authors, study participants, and the University of Alabama?
A With respect to the data or documents?
Q Both.
A Okay. We can handle the -- I'll

talk about the data first.
Q Okay.
A When we conduct a research study, as you're probably better familiar than I, it has to be approved by an institution or review board at the University of Alabama at Birmingham. And to participate in this particular study, there's a form that contains risks associated with participating in the study, it describes the details regarding the study, et cetera. And in that document it states that any data that is produced in our conversations with the patient or abstracting from their medical records will only be viewed by the individuals listed on that IRB approval form that is the principal investigator of the study as well as collaborators, Dr. Vaphiades, Dr. Cynthia Owsley, et cetera.
And so to provide that data would violate that agreement that we have with the patient and with the university who approves the study.
Q In other words, that would be -- that would refer to what, the abstracts that you and your co-researchers created from the medical

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records?
A The hard copy, the information comes from the actual medical record, the patient's actual medical record into an electronic database. In some instances, I don't recall exactly in this study, the information moves from the medical record, the paper medical record to a paper abstraction form and then into the database. So what I'm referring to here is paper medical record abstraction form, should there be one, as well as the electronic data itself.
Q Is the information coded in such a way as to prevent patient identification?
A The information is --
Q In other words, the patient identifying information is removed?
A Oh, absolutely.
Q Uh-huh. And it's your understanding that the confidentiality agreement that you provide to the patient would prohibit the disclosure of any portion of this trail of records from the original source material into the electronic database?
A Will you say that one more time?

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Q Yeah. What I'm trying to understand, is it your understanding that the confidentiality agreement that the institution provides to participants in the study protects from disclosure the entire chain of information from the original source material all the way to the tables that are stored in the electronic database?
A That is my understanding.
Q And besides the medical records, there were, I guess, interviews that were conducted of patients?
A Yes. That's correct, yeah.
Q And were there promises or -- strike that.
Were there any kind of confidentiality agreements or representations?
A It's the same -- the individual signs one Consent to Participate Form that covers our abstraction of their medical record as well as the conversation that we have with them regarding alcohol, smoking, Viagra, et cetera.
Q Is it your understanding that your confidentiality obligations would preclude

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turning those documents over to counsel even where counsel in this case are subject to a confidentiality order that prevents disclosure of information produced during the course of the litigation?
MR. OVERHOLTZ: I'm just going to object to the question to the extent that it calls him to make a legal conclusion. To the extent he can provide his understanding from the University, that's fine, but --
THE COURT: I'll overrule that if he can answer it.
A I'm afraid I can't answer it.
Q Let me step back. You notice that in the documents that you -- that were provided -- some of the documents that were provided to you by plaintiffs' counsel, there's a confidentiality stamp on that and a statement on the footer that indicates that it is subject to a confidentiality order in this litigation?
A That's right. You've pointed that out, yes, sir.
Q And we established off the record that you had not yet signed a confidentiality agreement, and we'll get that bit of

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housekeeping done. But in any event, you understand that the lawyers in this case are bound by a court confidentiality order if the information is properly stamped pursuant to that order?
A If you're telling me that's so. I'm not familiar with the nature of a confidentiality order, but that --
Q Okay. And my question for you with that background is whether it's your understanding that your confidentiality agreement with participants in the study would preclude giving, disclosing the data to the lawyers in this case bearing in mind that it would be subject to a confidentiality order imposed by the court?
A Gee, I guess I would have to check with the UAB risk management to answer that question. I guess I don't feel qualified to -- I don't -- I mean, I know the consent form, and we do them quite frequently, but I'm almost certain it makes no reference to a court-imposed confidentiality order. I guess I would feel more comfortable talking with the folks at risk management about how they would interpret your

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question and the form that the patient signed.
Q Just one more question. There's also a reference in this letter that we've marked as Exhibit 20 to -- disclosure of the underlying documents would infringe upon Dr. McGwin's proprietary rights. Do you know what that refers to?
A I'm going to infer that it refers to the actual questionnaire that was administered to the study participants.
Q Okay.
A Not having written the letter, I --
Q Okay. Dr. McGwin, so I understand that there's -- counsel interposed an objection to Specification Number 18. The other -- did you bring the other documents that were requested by the subpoena?
A The specific documents?
Q Yes.
A I think the only one that's listed is my paper.
Q No. It starts on -- Attachment A starts with Question Number 1, all documents and materials, published or unpublished, on which you intend to rely as a basis, in whole or part,

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for your opinions?
A The only thing that I did not bring, and I discussed this with the gentlemen, were some depositions that were really long of a Rachel Sobel and a -- what is the fellow's name?
Q Greg Gribko?
A No, no. He was a --
MR. OVERHOLTZ: Steve Watt?
Q Steve Watt? We can play 20 questions. Now we are going backwards. You are asking me the questions.
A I apologize.
MR. OVERHOLTZ: It would either be Gribko, Watt, Osterloh --
A That's it. That's it. Sorry. Osterloh. I'm sorry. There were so many --
Q So you were provided copies of deposition transcripts?
A Those two, yes, sir.
Q Those two, Rachel Sobel and Ian Osterloh. And you read those?
A Yes, sir.
Q Okay. And you didn't bring those with you?

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A That's correct.
Q Did you make any notations on those?
A No, sir.
Q And then other than those documents and other than Specification 18 to which there was an objection, did you bring with you today the other documents that respond to the subpoena?
A I believe I did, yes, sir.
Q And that's in this binder?
A That's correct.
Q What we'll do -- anything else besides what's in the binder?
A Did I rely on anything else other than what's in the binder?
Q Is there anything else that's responsive to the subpoena besides what's in the binder?
A No, sir. Can I finish my thought from before? I just wanted to say there are things in the binder that I relied -- that I've read as background material just generally.
Q Just as an example -- we're going to go through -- I only had a minute to look at your binder before we started the deposition,

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but I noticed as an example you had expert reports from plaintiffs' experts in other litigation --
A That's correct, yes, sir.
Q -- Dr. Schang, Dr. Moye, others having nothing to do with Viagra and NAION, correct?
A That's correct.
Q So why did you look at those documents?
A This is my first deposition and this was my first expert report, and the gentlemen provided me examples, two of which were from a colleague and mentor of mine, Dr. Jeffrey Roseman, as a form of guidance for writing my own document.
Q Okay. Let's ask a couple of questions here. When were you first contacted by plaintiffs' counsel?
A I have an e-mail here dated Wednesday, February 28th of 2007, which indicates that I had spoken with a Neil Overholtz and I remember that Mr. Jason Richards was also on that call. And this is -- I believe that was our first communication.

Q Okay.
A And this e-mail.
Q Okay. And you had -- I know in your materials that there were several pieces of e-mail correspondence and perhaps letters. Did you bring those with you?
A Yes, sir.
Q Okay. Did you have in-person meetings with Mr. Overholtz or any of the counsel for the plaintiffs?
A Yesterday we met at 2:30 in the afternoon.
Q Prior to yesterday, did you have any --
A No, sir.
Q So you didn't know what Mr. Overholtz looked like?
A No. No, sir.
Q Or any of the plaintiffs' attorneys?
A No, sir.
Q I won't ask the next question that comes to mind.
How long did your meeting last yesterday?
A Approximately two hours.

Q Okay. Did you review any documents at the meeting?
A Yes, sir. We reviewed -- to say that we reviewed, I went through this binder with them showing them the organization of it and pointing out, generally, what was in here, including the e-mails that we just discussed.
Q If you can do it reasonably succinctly, tell us what the logical organization of the binder is.
A Oh, goodness. The first section is a summary of various dates and specific things that I read or things that I prepared and the amount of time it took me to do those activities.
Q Okay.
A The second section is my expert witness report. The third section is our paper, which appeared in the British Journal of Ophthalmology, as well as the related paper that I've described previously on sleep apnea.
The next section is my curriculum vitae. The next section is a series of papers -- one, two, three, four -- which includes the original Bradford Hill paper as

well as two publications highlighting where people frequently misinterpret his criteria. And I found these particularly useful in preparing my document, so I added them in here.
The next section are the expert witness reports that you referred to. There are four in here.
Q That would be by Dr. Harris, Dr. Kimmel, Dr. --
A No, no, no. Sorry. These are the ones from the prior cases.
Q Oh.
A Dr. Farquhar, there are two by Dr. Roseman.
Q These were the exemplars --
A Yes, sir.
Q -- that had nothing to do with Viagra or NAION but they were as exemplars for expert reports?
A Yes, sir. I'm sorry.
The next section is the material that I received from Neil and Jason regarding, goodness, communications from Pfizer. There is a -- some reports in here about their work on NAION and Viagra. There's a document in here

from the FDA, a memo.
Q These are documents that were produced by Pfizer in the course of the litigation that had the confidentiality stamp on them?
A Most of them have the confidentiality -- some of them do not.
Q Okay. Good.
A And these are -- I'm not sure if there are more of them, but these are the ones that I received.
Q This was some group of documents that were provided to you by Mr. Overholtz?
A That's right, or Mr. Richards.
Q Okay.
A The next section is material, literature, published literature, not including my paper because it is in the other section, on Viagra and ophthalmology but mostly the case reports that we've been talking about -- the Margo paper, the other Pfizer paper that we talked about. What I consider this to be, the section, the literature section, the published evidence section.
Q Okay.

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A And it's just sort of complete as -- backs up the materials, the references that I used in my paper. There are some other studies, case reports in the literature that I don't think I relied upon and didn't print them out. And then the next section are the ones that -- the expert witness reports that you referred to. And there are four of them. And as I pointed out to you, there is one that printed out kind of funny, but --

Q Where the attachment for some reason when you printed it was blacked out although when you read it on the screen --

A That's right.

Q But the attachment was just the CV?

A I believe the part that is blacked out, for whatever reason -- the PDF looked fine on the screen. On here it just printed out black.

Q Sure.

A And in the front part of this binder were the e-mails that I've referred to. And it's basically -- there are three of them, and I kept this one to make sure I had the date as to the time that we first communicated. And then

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this is a request for an hourly rate as well as a request for other cases in which I've testified in the past, which I've sort of kept to document that they had asked me for that information. And then another is an e-mail wherein they -- it looks like from this e-mail, from the attachment listed here, this is where they sent me the expert witness reports that weren't related to this case. And I also kept this because it has their telephone numbers on it.

Q Have you worked on any other -- as a litigation consultant in any other matters?

A I'm not sure of the definition of the term.

Q Have you been -- in any other matters, have you given expert assistance to attorneys?

A Does that mean writing an expert witness report?

Q No. It means any form of assistance.

A So somebody contacting me asking me to look -- yes, sir.

Q I mean, but not an initial -- I

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mean, not just, gee, are you available, but where you provided some substantive assistance to an attorney?

A Yes, sir.

Q Okay. And what matters were those?

A The specific name of the case or just the nature of the case?

Q Let's start with the nature of the case.

A There was -- both of them actually involved eye injuries in motor vehicle collisions in which I've done a lot of research. One was a case, a -- one was a case on an eye injury related to an air bag deployment. And the issue at hand was whether the woman at hand, whether her eye injury was sustained because of the air bag being deployed or whether the eye injury was sustained due to some other mechanism.

The other case was a case in South Dakota, I believe, wherein a young woman was involved in a side impact motor vehicle collision in which she was the passenger. And the issue is she was unbelted and her air bag -- pardon me, the air bag did not deploy. And the

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issue at hand was whether, if the air bag had deployed, the observed injuries would have been different in pattern.

Q Okay. And those are the only cases that you've consulted on besides this case?

A That's correct.

Q Okay. You indicated that there were, I think, three pieces of e-mail correspondence that you had with the plaintiffs' attorneys. Was there any other correspondence of any type whether it was e-mail correspondence or other correspondence?

A We e-mailed back and forth, yes, sir.

Q But other than these three e-mails, was there any other e-mail correspondence?

A Yes, sir.

Q There was?

A Yes, sir.

Q And where is that?

A The actual e-mails?

Q Yes.

A Oh, I deleted them.

Q Oh. How many e-mails were there that you deleted?

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A Well, there was probably one e-mail with every -- each of these Pfizer documents that they sent me, the ones with the protective orders. And, you know, they might have sent those maybe a couple in a single e-mail and then there were some that came towards the end in individual.
Q In other words, they were e-mails that were -- acted as covering e-mails that transmitted attached --
A Yeah, see attached.
Q See attached?
A Yes, sir.
Q Were there any other e-mails that were -- that had any kind of substantive communication?
A Oh, no, sir. It was made clear that all the substantive communication was verbal.
Q Okay. And what were the substantive verbal communications that you had? Were there phone conferences that you had --
A Yes, sir.
Q -- with plaintiffs lawyers?
A Yes, sir.
Q Are there any kind of records of

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when those phone conversations took place, how long they lasted?
A I don't have any formal records of those. I would have to go to my calendar -- I don't have them here. I would have to go to my calendar to see when they took place. But often it would be -- they would send me something and we would -- you know, are you available this afternoon? And I would reach them or they would be available to speak.
Q Did you keep time records that reflected when those calls took place?
A I didn't log the time that we spoke on the telephone, no, sir.
Q How many phone calls would you estimate there were?
A Total number of phone calls?
Q Yes.
A Oh, goodness, maybe half a dozen.
Q Okay.
A And that probably included a few recent short phone calls about setting up this particular meeting in terms of my availability.
Q In terms of substantive communications, tell me what you remember of

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discussing the substance of the case.
A Sure. Most of the discussion was -- well, I can go chronologically if that would help.
Many of the initial discussions were about how to prepare an expert witness report. So we discussed sort of the organization and the format of the ones that they sent me -- Dr. Roseman's report, some of the others -- more educational on my part.
As the material -- when I say "material," the section, the protective order information, as that started to come through, I would digest it as rapidly as possible and we would have a conversation about my interpretation of it. They would generally ask me specific questions about my thoughts and feelings on this part of it, very much like the questions that you've been asking here today.
And as we got towards the deadline for providing the expert report, we talked about the exact content of it and then probably some ancillary conversations about do you want it faxed, do you need an original hard copy, et cetera.

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Q What was the process for preparing the report?
A My process for preparing the report? Well, as I said, I read -- I had read plenty of the literature already, but it had been quite a while because by the time the article came out it -- things had moved on. So I reacquainted myself with much of this literature here.
There had been several new studies. The Pfizer study had come out, so I obtained information regarding that. I read through Dr. Roseman's and the other expert witness reports to kind of -- it sort of helps knowing what the document is supposed to look like in sort of preparing my thoughts. I digested this material which -- and I took notes on it, and I think I pointed those out to you. The notes are here. There are some notes, handwritten notes on this material here (indicating).
Q Just so it is clear on the record, you are referring now to the documents that you had received from counsel that basically came from Pfizer's files?
A That's correct. That's correct.

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I reacquainted myself with the Bradford Hill literature. Basically, I read as much material as I could and then sat down and composed my report. Per my usual format, I usually sit down, compose my thoughts very rapidly, type them out, let it digest for a day, if not more, and then go back and reread it and make any necessary changes. And I probably edited it for grammar and things of that nature.

Q Did you share any drafts with plaintiffs' counsel?

A I believe I did share a draft with them.

Q And did they get back to you with comments?

A Yes. We had a telephone conversation, I explicitly recall, about the document.

Q And what were their comments?

A Their comments was that it was very good, that it addressed all of the relevant issues, the format, which was a big concern because this was new to me, was fine. They suggested a couple of grammatical changes. I used -- I'm an epidemiologist. I wrote like an

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epidemiologist, and there were some terms that they asked if I could translate into lay language, which I did to the best of my ability that it wouldn't detract from the point I was trying to make.

But it was -- as I recall, there were very few changes from what I considered to be the final version to what I -- what you ultimately see here.

MR. SLONIM: Okay. It's about 12:25. I think this might be a good time to break.

VIDEOGRAPHER: The time is 12:23. We are off the record for lunch.

(Lunch recess was taken.)

VIDEOGRAPHER: The time is 12:59. I changed tapes while we were at lunch. This is the beginning of Tape Number 5. We are on the record.

Q (By Mr. Slonim) Dr. McGwin, do you agree with me that no epidemiological study no matter how well done is perfect, correct?

A I do, yes, sir.

Q Every study, regardless of how well it is done, has flaws and limitations; is that

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right?

A Yes, sir.

Q And as an epidemiologist, I take it you're familiar with the term "bias"?

A Yes, sir.

Q And as used by epidemiologists, what does bias mean?

A It means some sort of error introduced into the study either advertently or inadvertently. There are a variety of different types of bias, selection bias or recall bias. But it is basically a distortion -- or pardon me. It results in a distortion of what would be considered the true results.

Q Perhaps another way of expressing it might be that bias refers to error other than random sampling error that can compromise the validity of a study. Would that be fair?

A Yes, sir.

Q And if bias is present in a study, you might find an association between an exposure and a disease when in fact there is no association, correct?

A Yes, sir.

Q It can go the other way as well?

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A That's correct.

Q I don't know if you mentioned it when you listed several types of bias, but there is one type of bias known as recall bias; is that correct?

A Yes, sir.

Q What is recall bias?

A Recall bias is generally a situation where one group of study subjects, if we use the case-control study as an example, provides information or recalls information differently than the controls would recall information. And that differential in their recollection of information produces a bias that can push the results either towards or away from --

Q If the cases have a better, sharper memory of the exposure than the controls, for instance, that would go to find an association when perhaps there isn't a real association?

A That's correct.

Q When were your telephone interviews of the cases and controls conducted?

A Could I have my folder back, or can I have my paper?

Q Is that in the paper?

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A It will help me jog my memory.
Q The paper refers to a January 2000 to February 2004 time frame. And I don't know if that -- I couldn't tell if that's when the interviews were done.
A Did you say January 2000 to February 2004?
Q Yes.
A Yeah. That is not when the interviews were done. That was the time period for which we obtained the patient listing that we've discussed previously.
Q Okay.
A If --
Q Would it help to see the other paper that you wrote, the apnea paper?
A Yeah, it might. In one of the two papers, we refer to the -- I believe we refer to it. If you could just give me one second.
Q Sure.
A I don't see the exact dates in here. It was accepted for publication in October 2005. Can I give you a range?
Q Yes.
A Oh, okay. I would say given that

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the list was truncated February 2004 and knowing that -- the delay between data resources, I want to say we probably started interviewing probably soon after February 2004. And depending on the workload in the clinical research unit, the interviewing could have taken a period of three to six months including callbacks and things of this nature.
Q Your best recollection, then, is that the interview would have been taken -- the interviews would have taken place sometime after February 2004; is that right?
A Oh, absolutely after February 2004, yes, sir.
Q Okay. You're not quite sure how long after?
A Yeah.
Q And then the interviews, they started at some point and then they continued for several months?
A Yes. Our general -- we have several research projects going on simultaneously, but what we tend to like to do is to make sure that we don't string out the process of interviewing for any one study over a year or two,

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particularly for a study of this size. It tends to cause problems.
So for a study of this size, I can tell you that our usual timeline for patient interviewing, obtaining callbacks is probably between three to six months. And I'd be surprised if it were as long as six months.
Q Okay. It's correct that by February 2004 there had been articles in the medical literature and in the media reporting NAION cases among men taking Viagra, correct?
A I would say yes to those in the literature. I'm not familiar with the dates of those that were in the media.
Q Fair enough. You're certainly aware of the fact that there had been a number of case reports and articles in the published medical literature about a possible association between Viagra and NAION prior to February 2004?
A Yes, sir.
Q Okay. And you indicated that the patients that you recruited for the study were patients that had been seen by ophthalmologists and neuro-ophthalmologists at the University of Alabama at Birmingham Ophthalmology Center?

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A Yes, in the Department of Ophthalmology at the University of Alabama at Birmingham.
Q And you agree that ophthalmologists at University of Alabama at Birmingham were aware of the medical literature and case reports of NAION among Viagra users prior to February of 2004, correct?
MR. OVERHOLTZ: Objection. Lack of foundation and calls for speculation.
THE COURT: Overruled. You can answer if you're able.
A I am aware that Dr. Vaphiades was aware of that literature. The other neuro-ophthalmologist that I mentioned, Dr. Lanning Kline, I don't know that he and I ever actually discussed that literature.
Q But ophthalmologists at the University of Alabama Medical Center and at the ophthalmology clinic make it a practice to keep up-to-date with the medical literature, do they not?
MR. OVERHOLTZ: Objection. Speculation, lack of foundation.
THE COURT: Overruled. You can

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answer, Doctor, if you are able.
A I don't know whether my colleagues keep up with the literature.
Q Do you agree that if ophthalmologists who were aware of case reports and articles in the medical literature of reports of NAION among Viagra users saw a patient with NAION, they were likely to have asked the patient about Viagra usage?
A Oh, I can't say what they would or would not have done when they saw such a patient.
Q It's a reasonable thing to think that any ophthalmologists who knew there had been reports of NAION among Viagra users and then seeing a patient in the clinic with NAION would think to ask the patient whether or not he had taken Viagra prior to the NAION; isn't that correct?
MR. OVERHOLTZ: Object to the form. Calls for speculation.
THE COURT: Yeah, I'm going to sustain that.
Q I want you -- strike that.
Given the fact that there were case

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reports in the medical literature about NAION among Viagra users, do you agree that cases might have been more likely to recall Viagra usage than controls?
A Yes, sir.
Q Okay. And the effect of that would be to find an association that was not real, correct?
A That's correct.
Q Okay. There's another type of bias called interviewer bias, correct?
A Yes, sir.
Q What is interviewer bias?
A This is -- it's similar to recall bias in that the person conducting the interview would have a reason for probing one group of patients, in this case the cases, more than they would probe the controls. And they would do this because they knew that -- I'm trying to think of a good example. They knew that the person perhaps was exposed or they had reason to think, well, there is this hypothesis out in the literature and these -- I know that these patients have NAION or NION and maybe if I ask a little bit harder --

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Q You'll get the information?
A -- you'll get the information you want, and they have no cause to do that in the controls. And it produces results similar to the one we just discussed.
Q And in your study of Viagra and NAION, Dr. McGwin, I take it from your description of the methods that the interviewers knew whether the person they were interviewing was a case, meaning that the person being interviewed had experienced NAION, or a control, meaning that the person being interviewed had experienced some condition other than NAION, correct?
A The interview, the survey instrument contained a section about their experience with NAION because we were interested in -- although it's not in these papers -- quality of life issues. And that was relevant if you had NAION, but not -- and so by default we couldn't avoid that.
Q So in other words, the answer to my question is that yes --
A Oh, yes.
Q -- the interviewers knew the status

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of the person being interviewed as to whether he was a case or a control?
A Yes, sir.
Q Okay. And because of that, as you indicated, the interviewers may even unconsciously have questioned the cases differently than the controls regarding their exposure to Viagra, correct?
MR. OVERHOLTZ: Object to the form. Lack of foundation.
THE COURT: I'll sustain.
Q Dr. McGwin, the fact that the interviewers knew the status of participants in the study as either cases or controls might have led to interviewer bias, correct?
A That would be true if they knew that we were interested in Viagra as a risk factor.
Q Okay. In your case, did the interviewers know that you were looking at the hypothesis that Viagra might be linked to NAION?
A No, sir.
Q There had been reports, though, in the medical literature at that time that indicated that Viagra was --
MR. BECNEL: Objection,

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repetitious.
THE COURT: Overruled. You can answer if you're able.
A Yes, there had been reports up to that -- previous to the time we had started.
Q If the interviewers questioned the cases who they knew had NAION more closely about exposure to Viagra than controls, the effect of that would be to find an association even though such an association might not really exist, correct?
A A positive association, yes, sir.
Q And that would be interviewer bias, correct?
A It would be.
Q Okay. Are you familiar with a term called "selection bias"?
A Yes, sir.
Q And what is selection bias?
A Selection bias is often a problem in case-control studies where one selects cases or controls somehow systematically differently. One of the frequent examples that's given for selection bias are hospital-based case-control studies where we select cases of cancer or

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whatever the disease may be from a given hospital. And the hospital has a catchment area of a certain radius or geographic area, yet we select our controls in such a way that they aren't representative of that same geographic area. And that can result in selection bias if the exposure somehow is also related to that, in this example, that given geographic differential.
Q Now, the controls in your study were selected from the same tertiary care clinic as the cases rather than from the general population without NAION, correct?
A That's correct.
Q And if there is something different about the population of patients that gets referred to a tertiary care clinic than the general population, that would introduce a selection bias, correct?
A Yes, that's true.
Q Another thing that I noticed in your study is that you excluded cases with prior NAION but not controls with prior NAION, correct?
I misspoke. Let me withdraw the

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question and rephrase it.
In your study, Dr. McGwin, you excluded cases with prior ION, that's ischemic optic neuropathy, but you did not exclude controls with prior ION; is that correct?
A That is correct.
Q And if the history of prior ION affected the usage of Viagra, that would artificially reduce the number of controls exposed and artificially, therefore, increase the odds ratio, correct?
MR. OVERHOLTZ: Objection. Lack of foundation.
THE COURT: Overruled. You may answer if you are able.
A That would be correct.
Q Are you familiar with the type of --
MR. SLONIM: I noticed in the question -- this is to the court reporter. I noticed in the question on the LiveNote transcript that you wrote down AION, A-I-O-N. In that question it should be ION, just I-O-N.
MS. LESKIN: That group of questions.
MR. SLONIM: Yeah. And it makes a

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difference.
COURT REPORTER: Okay.
MR. SLONIM: Thank you.
Q Dr. McGwin, are you familiar with a type of bias called "nonparticipation bias"?
A Yes, sir.
Q And what is that?
A Oftentimes when you conduct a study as in ours, you have a group of people who are eligible for participation. And due to a number of reasons -- lack of interest, lack of trust -- certain participants don't agree to participate in the study, and -- which is fine and expected, but the concern is not so much that they failed to participate, it's that those who do and do not participate are systematically different and that difference is different between the cases and controls resulting in a somehow skew or a bias in the measure of association.
Q And referring now to your study, first of all participation was voluntary, correct?
A Absolutely, yes, sir.
Q Okay. And both cases and controls, a certain percentage of them refused -- people

that were eligible refused to participate, correct?
A That's correct.
Q Okay. And specifically you identified at the outset 88 cases of NAION among males and females, but 15 of those cases refused to participate, correct?
A Yes, sir.
Q And if you do the arithmetic, I don't know if you have your calculator, but if 15 out of 88 refused to -- declined to participate, that's a nonparticipation rate of the cases of 17 percent, correct?
A Yes, sir.
Q Okay. And you also identified 130 potential age and sex match controls, but 42 of those refused to participate, correct?
A That's correct.
Q And 40 over 132 (sic) is a nonparticipation rate of 32 percent, correct?
A That's correct.
Q So the nonparticipation rate of the controls was about double that of cases?
A That's correct.
Q Okay. Cases meaning cases of people

that actually had NAION, correct?
A That's correct.
Q Okay. And so people with NAION who used Viagra might have been more interested in participating in a study than controls who had an eye condition other than NAION who used Viagra, correct?
MR. OVERHOLTZ: Object to the form. Lack of foundation.
THE COURT: Overruled. He can answer if he's able.
A Yeah. Hypothetically, sure, they may be more likely to participate.
Q And if that were the case, the effect would be to find an association or a higher odds ratio than the true association, correct?
A As long as the controls weren't similarly affected, yes, sir.
Q Okay. I want to ask some questions about Table 1. We've referred to that a couple of times previously.
A Sure.
Q Let me just get my copy. As we've discussed, this identifies nine different

demographic or medical characteristics that you looked at for each of the cases and controls, correct?
A Yes, sir.
Q Did you perform analyses to assess whether exposure effects differ in each of these nine -- with respect to each of these nine categories?
A Did we conduct stratified analyses?
Q No. What I want to know is whether or not you looked at whether there was differential exposure.
A Oh, differential exposure. I understand the question, yes, sir. It is likely that we did.
Q Do you recall?
A Not specifically; although, it is my general course to do such analyses.
Q So just to take an example, did you analyze the subgroup of patients that had diabetes to see whether or not there was differential exposure to Viagra between cases and controls?
A I likely did, yes, sir.
Q And do you think you did the same

thing with coronary artery disease?
A Yes, sir.
Q Basically you think you ran down the list and did an analysis to see whether there was differential exposure in each of -- for each of those characteristics?
A Yes, sir.
Q The only characteristics on which you report your analysis of differential exposure is for -- strike that.
What were the results for the diabetes and the coronary artery disease patients in terms of their differential exposure? Did they have a statistically significant increased risk of NAION?
A Are you asking whether diabetics have an increased risk of NAION?
Q Diabetics -- I'm asking whether diabetics who used Viagra had a statistically significant increased risk compared with diabetics who did not use Viagra?
A I don't recall the results exactly, but given that that's very similar to the data we present in Table 2 and we didn't include it in the paper, I'm going to -- I'm going to guess

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that it probably was not statistically significant.
Q The same thing with coronary artery disease?
A Yes, sir.
Q And each of the other categories?
A Yes, sir.
Q The only -- the only data that you report concerns patients who used either Viagra and/or Cialis and had a history of myocardial infarction or who used Viagra and/or Cialis and had a history of hypertension, correct?
A Yes, sir.
Q So that's called a subgroup analysis, correct?
A One could refer to it that way. I would generally refer to it as either effect modification or interaction. To my mind, a subgroup analysis is really a whole analysis limited to a group of individuals such that we would have conducted a study wherein it was limited just to people with MI, but I've often referred -- seen these analyses referred to as subgroup analyses.
Q It's correct that the more questions

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that are asked of a set of data, the more likely it is that some will show a statistically significant difference even if there is no real underlying difference, correct?
A Yes, sir.
Q And, in fact, if you partition a set of data into small subsets, you make it more likely that some subset will show a statistically significant difference even if there is no real underlying difference, correct?
A Yes, sir.
Q And indeed, if you test enough subgroups, a false positive result will emerge from the data purely as the result of chance, correct?
A Will result or can result?
Q Yes, will result. If you test enough subgroups --
A If you test enough subgroups, yes, sir.
Q -- you're going to get it, right?
A Yes, sir.
Q And isn't it the case that at the conclusion of a study, if some subgroup shows a statistically significant effect, that after the

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fact one can come up with a medical explanation to fit the observation?
A Sure, yeah. Yes, sir.
Q And -- strike that.
(Deposition Exhibit Number 22 was marked for identification.)
Q We've marked as Deposition Exhibit Number 22 an article by Schulz and Grimes entitled "Multiplicity in randomized trial II: subgroup and interim analyses" published in Lancet in 2005. Have you seen this article before?
A No, sir.
Q Why don't you -- why don't you take a couple of minutes and just read the abstract and get a flavor for the article?
MR. BECNEL: Well, let me enter an objection. If you're going to show him an article he hasn't read, we are not going to let him read the abstract. We are going to let him read the article if you're going to question him.
Q Dr. McGwin, if you need --
MR. BECNEL: Counsel, that's my instruction. That is my instruction.

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THE COURT: No. I'll instruct him. I understand the objection.
MR. SLONIM: Judge Borg, may I just say one thing?
THE COURT: Well, yeah. I haven't even ruled yet, though. So are you going to --
MR. SLONIM: I would say this: Of course if the witness wants -- if the witness needs to read the entire article to respond to a question, of course he should do that. I don't think it's --
THE COURT: So is there a question to him?
MR. SLONIM: Not yet. I just want him to glance through the article, and I'm going to frame a question.
THE COURT: All right.
MR. SLONIM: And if the witness needs to spend more time reading the article, I have no objection to that.
MR. BECNEL: Judge, we have a case management order that says we are not allowed to pop new things on witnesses or counsel, that if you are going to use something in the deposition, we are supposed to be given it in

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advance. You guys brought that up.
MR. SLONIM: Counsel, shame on you. Shame on you. We of course disclosed this to Mr. Overholtz and Mr. Becnel. Of course we disclosed this. We sent them an e-mail five days ago. Shame on you.
THE COURT: Well, you know what? Let's stop the back-and-forth on that. If it was disclosed -- and you represent that it was, Mr. Slonim. Is there any --
MR. OVERHOLTZ: It was disclosed but not provided.
THE COURT: I'm sorry?
MR. OVERHOLTZ: It was disclosed but it wasn't provided.
MR. BECNEL: This is first I've seen this.
MR. SLONIM: Your Honor, we have a copy of the e-mail right here.
THE COURT: Mr. Overholtz just said it was disclosed.
MR. OVERHOLTZ: I said it was disclosed.
THE COURT: He just said it was disclosed.

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MR. OVERHOLTZ: It just wasn't -- we didn't have a copy of it.
THE COURT: Go ahead with your question.
MR. SLONIM: It was a false citation.
THE COURT: Go ahead with your question.
Q (By Mr. Slonim) Dr. McGwin, take a minute, please, and look at this article.
MR. OVERHOLTZ: There is no reason to mark that as an exhibit. Come on, guys. I said it was disclosed. Everybody knows it was disclosed. Good Lord.
MS. LESKIN: The issue is the witness had a copy of the list in the papers he brought. So --
MR. SLONIM: We are going to put it in the record.
MR. OVERHOLTZ: What does that have to do with anything?
MR. BECNEL: I want to put it on the record. I want to put it on the record. Last Friday we were in a deposition and then we were stuck in airplanes until all hours of the

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morning on Saturday, and then we were required to go to Minnesota all day on Monday and Tuesday. And so to sit down as you as a professional saying you disclosed something that was published in 2005 that you had five days before knowing what was going on, that's just unconscionable and lacks professionalism.
THE COURT: Okay. We're going to stop that right now. No more back-and-forth about who's professional and who isn't. Let's get a question to the witness.
Q (By Mr. Slonim) Dr. McGwin, let's mark as Deposition Exhibit Number 22 -- 23 an e-mail that you brought with you from your file.
(Deposition Exhibit Number 23 was marked for identification.)
Q Can you identify that as an e-mail that you received?
A Yes, sir.
Q Okay. And that's an e-mail you received from Mr. Overholtz, correct?
A That's correct.
Q And it forwards an e-mail that Mr. Overholtz received from Ms. Lori Leskin,

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correct?
A That appears to be the case.
Q Read the first sentence of Ms. Leskin's e-mail, please.
A Gentlemen, pursuant to the Court's order regarding the deposition protocol, we provide you with a listing of documents we reasonably expect to use during the course of Mr. -- pardon me -- Dr. McGwin's deposition.
Q And would you please read then Item Number 9 on that list?
A Schulz, KF, Grimes, DA, Multiplicity in randomised trials II, subgroup and interim analyses, Lancet, Volume Number 356, pages 1657 to 1661, 2005.
Q And that's the same article that we have marked as Deposition Exhibit Number 22, correct?
A Yes, sir.
MR. BECNEL: Counsel, let me see a copy of that e-mail?
MS. LESKIN: For the record, that e-mail was sent to Mr. Becnel, Mr. Overholtz, and Mr. Hopper by me on June 7th, 2007, at 4:48 p.m.

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MR. BECNEL: Well, I've got it listed on the top as saying 6-14-07. You just printed it, is that what this is? Where is the e-mail?
MS. LESKIN: The witness brought that with him among materials he had.
MR. SLONIM: This is Mr. -- this is what Mr. Overholtz forwarded to the witness.
MS. LESKIN: Counsel, I'm lead counsel in this case. I'm the lead counsel.
MR. SLONIM: And you got a copy of this.
MR. BECNEL: I was taking depositions on Friday.
MR. SLONIM: The Court Order requires us --
MR. BECNEL: I understand how you practice law. I understand what you're doing.
MS. LESKIN: Mr. Becnel --
MR. BECNEL: We'll practice the same way.
MS. LESKIN: Mr. Becnel, you have no right to --
THE COURT: It's over. It's over.
MR. BECNEL: I've had enough of

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this.
THE COURT: It's over. Both of you, it's over. No more of that on the record. Get the question to the witness.
MR. BECNEL: We would like to take a break to read the document.
THE COURT: Well, he's going to ask a question before we do that.
MR. BECNEL: Well, I would like to read the document. I haven't had an opportunity to read it.
THE COURT: Go ahead and start reading it. Ask the question.
Q (By Mr. Slonim) Dr. McGwin, this article explains that conducting analyses of every subgroup and reporting only those that yield a positive result is a scientifically flawed methodology, correct?
MR. OVERHOLTZ: Objection. Lack of foundation. We need to take a break and let the witness read the full --
THE COURT: All right. You're going to take a break and read it, Counsel?
MR. OVERHOLTZ: And let the witness read it.

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MS. LESKIN: You know that there is a question pending.
THE COURT: That's what I wanted was a question pending.
THE WITNESS: Can I get the question just one more time before I start reading?
MR. SLONIM: Yes, yes.
Q This article explains that conducting analyses of every subgroup and reporting only those that yield a positive result is a scientifically flawed methodology, correct?
MR. OVERHOLTZ: So we are off the record?
VIDEOGRAPHER: No, we are still on the record.
MR. OVERHOLTZ: No, we're off the record.
MR. SLONIM: No, I want it on the record.
MR. OVERHOLTZ: He's going to take a break and go in the other room --
MR. SLONIM: We don't need any breaks.
THE COURT: Do you know what? Just

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a minute, folks. I'll tell you whether or not we are going to take a break.
Mr. Witness, do you need to read this article, Dr. McGwin? Would you like to read the article?
THE WITNESS: To answer this specific question, I don't believe I need to read the entire article, no, sir.
THE COURT: All right.
Mr. Overholtz and Mr. Becnel, have you both read the article?
MR. BECNEL: No, I haven't. I have not.
THE COURT: Mr. Overholtz, have you read it?
MR. OVERHOLTZ: No, I have not.
THE COURT: All right. How much time do you want to read it, gentlemen?
MR. OVERHOLTZ: It shouldn't take more than a few minutes.
THE COURT: All right. Then we'll stop the record for five minutes.
VIDEOGRAPHER: The time is 1:32 and we are off the record.
(Recess taken.)

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VIDEOGRAPHER: The time is 1:37 and we are back on the record.
THE COURT: Counsel there will be no further references from any one of you to any other about everybody else's professionalism. We are going to stick to the record, and we are going to ask questions and we're going to get answers.
And if you will recall from the Court's Order on the conduct of the depositions, the only objections are to the form, privilege, and responsiveness. Everything else is reserved specifically by the Court, and there are no speaking objections other than those. And there are no speeches from counsel.
You can proceed now. Repeat the question to the witness, please.
Q (By Mr. Slonim) Dr. McGwin, this article that we've marked as Deposition Exhibit Number 22 explains that conducting analyses of every subgroup and reporting only those subgroups that report a positive result is a scientifically flawed methodology, correct?
A That is correct.
MR. OVERHOLTZ: Objection. Lack of

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foundation.
THE COURT: Overruled. You may answer the question, if you're able.
A Correct.
Q In other studies that you, yourself, have conducted, Dr. McGwin, you have acknowledged that performing multiple subgroup comparisons, specifically and particularly when the subgroups are not defined a priori as a hypothesis that you are investigating means that chance cannot be ruled out as an explanation even if the association appears to be statistically significant, correct?
A That would be correct.
Q In particular, you recall that you did a study involving at-fault automobile crashes and medical conditions and medications taken by elderly people?
A Published in the American Journal of Epidemiology, 1990 --
Q Yes.
A Yes, sir.
Q Okay. And among other things, you found that elderly automobile drivers who used either calcium channel blockers or vasodilators

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had a statistically significant reduced risk of accidents, correct?
A I believe that's correct, yes, sir.
Q But you discounted those statistically significantly associations because they resulted from analyses of subgroups that were not specified as part of the original hypothesis being investigated, correct?
A Well, I guess those weren't subgroup analyses, per se. Those were simple risk factors.
Q But they were statistically significant results that you found that people that used calcium channel blockers or vasodilators had a statistically significantly reduced risk of at-fault automobile accidents, correct?
MR. BECNEL: Objection. Repetitious.
THE COURT: Overruled. He can answer.
A Yes. We found it statistically significant, yes.
Q But despite those findings, you noted in your article that those results could

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have been attributable to chance --
A Yes, sir.
Q -- correct?
Why could those results have been attributable to chance even though they were statistically significant?
A Well, chance is always a potential explanation for statistically significant results. There is variability with all of the statistical tests.
Q But in this particular case, you had done -- you had done multiple cuts through the data, and calcium channel blockers and vasodilators were a part of the multiple cuts through the data. And even though the results were statistically significant, you discounted them, correct?
MR. OVERHOLTZ: Object to the form. Foundation. If we are going to talk about the data analysis in this motor vehicle study, we ought to pull it out and look at it.
THE COURT: It is overruled. He may answer if he's able.
A By cuts to the data, we looked at a number of different risk factors. And I guess I

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just wanted to be sure that we don't shift gears from subgroup analyses to primary independent variables.
Q Sure.
(Deposition Exhibit Number 24 was marked for identification.)
Q What exhibit number is that?
A 24.
Q Dr. McGwin, we've marked as Deposition Exhibit Number 24 an article that you authored with others entitled "Relations Among Chronic Medical Conditions, Medications and Automobile Crashes in the Elderly: A Population-based Case-Control Study." This is the study that you and I have been discussing, correct?
A Yes, sir, uh-huh.
Q And turn, please, to page 430. And direct your attention to the second -- to the first full paragraph on the left-hand side. You wrote, "The results of this study reflect a large number of analytic comparisons. It is possible that some of the differences detected were the result of chance. For some comparisons such as those with respect to at-fault

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involvement in crashes and heart disease or stroke, there were definite a priori hypotheses. However, for others such as the differences with respect to the use of calcium channel blockers and vasodilators and at-fault involvement in crashes, there were no a priori hypotheses. Chance cannot be ruled out as a possible explanation for these findings."
So even though you found statistically significant reduced incidence of accidents among elderly drivers who used calcium channel blockers and vasodilators, you discounted those findings why?
A I don't necessarily think that we discounted them. I think what we did was we indicated that lacking any prior literature that they might be risk factors, lacking any good scientific foundation that calcium channel blockers might impair driving safety, one of the then possible explanations is that they are simply due to chance.
Q Okay. We had marked the Schulz and Grimes article. There are other articles in the scientific and epidemiological literature that explain that subgroup analyses are problematic

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because as you do multiple comparisons, you may get statistically significant results purely as a function of the subgroup and chance, correct?
A That's correct.
Q Okay. And let's just mark one or two of those other articles.
(Deposition Exhibit Number 25 was marked for identification.)
MR. SLONIM: Exhibit Number 25?
MS. LESKIN: Yes.
Q We've marked as Deposition Exhibit Number 25 an article by Yusuf and others entitled "Analysis and Interpretation of Treatment Effects in Subgroups of Patients in Randomized Clinical Trials." Is that article in front of you?
A Yes, sir.
Q And is that an article that you've seen before today?
A No, sir.
Q It was also identified on our -- actually this one was mentioned in Dr. Kimmel's expert report. Did you read Dr. Kimmel's report in this matter?
A Yes, sir.

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Q Okay. Turn, please, to page 95. In the middle of the page, the authors state, "While postulating subgroup effects a priori allows formal statistical hypothesis testing, much less credence is due to formulating hypotheses after examining the data. Such analysis smacks a betting on a horse after the race is over."
Do you see that, middle of the page?
A Yeah, I've got it.
Q Have I read it correctly?
A Yes, sir.
Q Okay. Do you agree that that is a problem with subgroup analysis where the subgroups are defined after the initial data collection is done?
A I think the analogy to betting on a horse is a bit overstated.
Q But you agree that that use of it, the coauthors have identified a methodological problem with subgroup analysis, correct?
A Yes, sir.
Q Okay. And there was another article we inadvertently attached -- oh, we took it off?

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(Deposition Exhibit Number 26 was marked for identification.)
Q We marked as Deposition Exhibit Number 26 an article by Sleight entitled "Debate: Subgroup analyses in clinical trials -- fun to look at but don't believe them."
This is also identified in Exhibit Number 23, correct, Dr. McGwin? Exhibit Number 23 was the e-mail.
A Yes, sir.
Q Okay. Referring your attention to the abstract, the author states, Analysis of subgroup results in clinical trials is surprisingly unreliable, even in the clinical trial. This is the result of a combination of reduced statistical power, increased variance, and the play of chance. Reliance on such analyses is likely to be more erroneous, and hence harmful, than application of overall proportional, or relative, result in the whole trial to the estimate of the risk in the subgroup. Plausible explanations can usually be found for effects that are in reality simply due to the play of chance. When clinicians believe such subgroup analyses, there is a real danger

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of harm to an individual patient.
Do you agree that Sleight has identified and characterized methodological flaws with subgroup analysis?
A Before I answer, you misspoke when you read the first sentence. You omitted the word "large."
Q Okay.
A Just for the sake of clarity.
Q Thank you.
A I believe that's correct.
Q Okay. Dr. McGwin, let me -- let's take a short break. Let me consult with my colleagues and see if we can wrap this up.
VIDEOGRAPHER: The time is 1:49, and we are off the record.
(Recess taken.)
VIDEOGRAPHER: The time is 2:00 p.m. I changed tapes. This is the beginning of Tape Number 6. We are back on the record.
THE COURT: Mr. Slonim?
MR. SLONIM: I have no further questions, Your Honor.
THE COURT: Mr. Overholtz?

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MR. OVERHOLTZ: Mr. Becnel is going to begin with our redirect.
EXAMINATION BY MR. BECNEL:
Q Doctor, until today, you didn't know who I was, did you?
A No, sir.
Q And you met me for the first time at lunch.
A Yes.
Q Other than seeing me?
A Other than seeing you walk in the room, yes, sir.
Q You've worked at UAB as a teacher and scientist; is that correct?
A That is correct.
Q You have no interest in the outcome of this litigation one way or another, do you?
A No, sir.
Q You were contacted after your paper was published by members of the plaintiffs' team; is that correct?
A That is correct.
Q Has Pfizer ever contacted you after you published your studies to say what you had found, why you found them, and what was going on

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with them?
A No, sir.
Q You've never heard from Pfizer?
A No, sir.
Q Are you aware that drug companies are required to provide warnings and warning labels to people who take their products; is that correct?
A I am aware of that, yes, sir.
Q And that's an ethical obligation as well as a legal requirement?
MR. SLONIM: Objection.
THE COURT: Overruled. You can answer it if you are able.
A I believe that's correct, yes, sir.
Q Because of safety, because of efficacy of the drug and because of the side effects that might occur --
A Yes, sir.
Q -- is that correct?
The literature -- were you aware of how this drug was first developed?
A No, sir.
Q Were you aware that this drug was developed as a drug for angina that had no

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effect on angina; and when they discovered it had an effect on impotence, they switched it to an impotence drug?
MR. SLONIM: Objection. Lack of foundation.
THE COURT: Overruled. If he's able to answer. He'll tell us whether or not he knows the answer.
A That kind of sounds familiar, but I can't say that it was knowledge that I have been carrying around with me.
Q Now, what kind of reputation -- scratch that.
You went to Harvard, which is one of the more prestigious schools, is it not, in your field?
A I believe people would characterize it as such.
THE COURT: If you are able to answer that one.
Q What are you doing having come from Harvard at UAB, and why?
A If your question is why did I come to UAB, I was interested in the area of injury epidemiology. And at the time, the Harvard

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School of Public Health did not have an interest in Ph.D. students who were interested in injury epidemiology. That is why I came to UAB in the first place. I haven't left since then, despite actually having been recruited to go back to Harvard, having been recruited to go to the University of Pennsylvania because people at UAB are nice. It's a great place to work.
Q In addition to that, what is the reputation of the school?
A I believe that the reputation of UAB is that it's a fine institution, both the medical school as well as the school of public health as well as the university in general. It's one of the better funded institutions from the NIH. It has a very good reputation medically. It does very well in standard metrics, the U.S. News and World Report, best doctors, best hospitals. It ranks very highly in transplant medicine and arthritis and rheumatology and a number of disciplines.
So I believe both from my own perspective but also using national benchmarks that it's a very highly rated institution.
Q You consider yourself a scientist.

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A Yes, sir.
Q You consider yourself a researcher more than anything else, do you not?
A I view myself as a researcher as well as a teacher, yes, sir.
Q As well as a teacher. Now, in addition to that, sir, you have a unique expertise in the field we are discussing right now, do you not?
A I believe that's correct, yes, sir.
Q There are only about a half a dozen in the whole country and maybe ten in the whole world that have your expertise; is that correct?
A There are very few card-carrying, that is, Ph.D.-trained epidemiologists who focus specifically on eye disease, yes, sir.
Q And how many would you think are in the U.S.?
A In the U.S., I'm familiar with six, six to eight individuals trained as Ph.D. epidemiologists who focus mostly or solely in eye disease.
Q How about in the world?
A I would say we could probably number it close to 12 or so total.

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Q Now, why did you begin studying this particular problem as a scientist, as a teacher, and as an epidemiologist?
A Referring to the Viagra question?
Q The Viagra-related issues.
A As we discussed earlier, we were pursuing a study on risk factors for NAION. And at the time, one of the, as we've discussed, issues that had come up in the literature was the role of Viagra. At the time we were working, there was no epidemiologic study. It was case reports, which are valuable in the terms of generating hypotheses. It is where most research begins, identifying an unusual combination of disease and exposure. That's not to say they don't -- they test the hypothesis. They don't do that.
So we inserted several questions about Viagra and Cialis. Levitra at the time hadn't hit the streets, and so we didn't include that into our questionnaire. The manuscript itself was not the primary focus of the study. I mean, clearly not. We included women. We were interested in risk factors in general.
The paper is a natural progression

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of scientific inquiry. It's -- we had the case reports. There was a hypothesis at hand, and we pursued it.

Q Now, you have written a report which you wrote entirely yourself; is that correct?

A That's correct.

Q Nobody from the plaintiffs' side or anywhere else had any influence in you writing that report?

A No, sir.

Q And no changes other than grammatical and showing you how an expert report had to comply with the federal rules did anybody give you any information to include?

A No, sir.

Q Nor did you get media trained, even though this is your first deposition?

A No, sir.

Q And we didn't spend weeks or days or hours preparing you for your deposition, did we?

A No. As I mentioned earlier, we met for at most two hours yesterday afternoon.

Q Now, your expert report has a critique of Pfizer's evidence in this case; is that correct?

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A That's correct. I believe it does.

Q And you have some major criticisms of that evidence of Pfizer; is that correct?

A Yes, sir, I believe I do.

Q All right. Will you give us the background of why you have that criticism as a scientist and as a teacher who specializes uniquely in this subject matter?

A Placed in the context of much of what we talked about today, most of the material I've been handed here are studies from the bottom of case reports and case series up through case-control studies and then a small cohort study. Much of the evidence that I was given was secondary analyses of clinical trial data, and we talked about that in the -- the author escapes me. We talked about it in the Pfizer publication this morning.

Many of the criticisms that we talked about with respect to my study, the ability to define NAION, the data from Pfizer suffers from the same problems. They didn't have formal clinical definitions of NAION in the data that they searched. There was no formal statistical evaluation of those hypotheses. The

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statistical power of the comparisons that were done was lacking. So in a sense in terms of its contribution to the science, it had many of the normal limitations you would see in epidemiologic studies, but it was secondary data. It was data that was being looked at in a very ad hoc sort of way.

Much of the other information that I was given was -- some of the more interesting pieces of material were recommendations to Pfizer about doing a case-control study. I believe there was a document from the FDA suggesting a case-control study. I believe there was a panel -- I don't know if it was an expert panel or a --

Q A scientific advisory panel?

A -- scientific advisory panel wherein they reviewed my study and they saw the same flaws in it that were discussed here and most of the same flaws that I admitted in the paper, yet still indicated that a case-control study would be feasible and somewhat doable.

So, again, that was the material that I read. It clearly indicated that our approach was a reasonable and valid one. The

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scientific evidence that they provided, the quantitative evidence was very weak and subject to even more of the limitations that we faced in our study.

Q And this particular drug has its purpose in society; however, it has limitations --

MR. SLONIM: Objection.

Q -- in its use; is that correct?

MR. SLONIM: Objection.

THE COURT: What's the objection?

MR. SLONIM: Form.

THE COURT: Overruled. You can answer if you are able, doctor.

A I believe Viagra does have its use in society. There are men that suffer from impotence who at least in my knowledge of the literature clearly benefit from its use. I believe it's also been used to treat premature infants with respiratory disease. I believe it's been used in situations such as that. So I would agree with you, yes, it has its purpose in society.

Q But it has its limitations depending on certain risk factors of men who are

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predisposed to some other disease or limitations according to the FDA, people with smoking habits and people with high cholesterol and people with previous heart-related problems, et cetera?
MR. SLONIM: Objection, Your Honor. Lack of foundation. There's no evidence for any of this.
THE COURT: Overruled. If he's able to answer it, he can say so.
MR. BECNEL: Counsel, let's get the exhibit number. I don't -- you didn't give me a copy. The exhibit number, the FDA advisory. Do you know what number that is?
THE WITNESS: 12. 11 and 12.
MR. BECNEL: I'm referring to the one from -- they had one from 6-11-07 and the earlier one in '05.
Q The people that shouldn't get this drug, at least according to the FDA, are people who have heart disease, are over 50 years old or have diabetes, have high blood pressure, have high cholesterol, smoke, and have certain eye problems.
MR. SLONIM: Objection, Your Honor. That's not what it says.

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THE COURT: Just a minute.
MR. SLONIM: Let him -- please let him read it.
VIDEOGRAPHER: Mr. Slonim, your papers are on your microphone. Thank you.
THE COURT: Do you want to state your objection again because I don't think the videographer got it.
MR. SLONIM: Yes. The objection, Your Honor, is that that is not at all what the document says.
THE COURT: Well, the document says what it does. It's overruled. And if you need to ask him a question coming back at him, you can do that. Overruled.
THE WITNESS: The document that I have as Exhibit 12 indicates that the groups that you mentioned -- heart disease, 50 years old, or have diabetes -- are people who are at -- have a higher chance of NAION, but I do not believe it makes specific reference to the use of Viagra, Cialis, or Levitra, at least the sentence as I'm reading it.
Q (By Mr. Becnel) Sir, tell me, in terms of your ultimate opinion, you have

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concluded in your summary and conclusion what in this case?
A May I read it verbatim?
Q Sure.
A This is in Section 4, page 7 of my expert witness report, the last sentence. Thus, in conclusion, to a reasonable degree of scientific certainty, it is my opinion that Viagra can cause NAION and other ocular vascular disorders.
Q And the basis of that is what?
A The basis of that statement is the entirety of the research that not only I've done but also the research that I've read on this topic as it refers to Viagra and NAION and case reports to the limited number of epidemiologic studies to the animal as well as basic science literature.
Q And you've read the work of Dr. Hayreh?
A Yes, sir.
Q Is he well respected?
A Yes, sir.
Q Where would you consider him in terms of this area of research and treatment?

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A I would say he's perhaps one of -- he is the leading researcher in this area.
Q And have you ever heard any criticism of him whatsoever other than from Pfizer's experts?
A Other than from Pfizer's experts, no, sir.
Q In the whole universe of your field of specialty?
A No, sir.
Q Now, is it more probable epidemiology-wise, medical-wise and scientific-wise that it is more probable than not that Viagra is associated with sufficient evidence that it can cause NAION? In other words, if you use the little scales of justice, what is more one way than the other?
A You said epidemiologically and medically.
Q Well, you are not a medical doctor, I understand.
A So I can respond epidemio --
Q Yes.
A Epidemiologically, I would agree with you that more probable than not that there

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is an association between Viagra and other ED medications and NAION.
Q Thank you. I have no further questions.
THE COURT: Mr. Slonim, anything else? Mr. Overholtz, do you have some questions?
MR. OVERHOLTZ: I've got just a couple of questions.
EXAMINATION BY MR. OVERHOLTZ:
Q Dr. McGwin, you were asked some questions by counsel regarding some studies that you had read for the first time today and seen regarding subgroup analysis.
A Yes, sir.
Q Your publication on the use of ED medications and the risk of NAION, Exhibit 3 that we've talked about, did you do a subgroup analysis in that paper?
A If we use the term generically, yes. I mean, the papers that were given to me, Exhibit Number 22, 25, and 26, use the term "subgroup analyses" in the context of a clinical trial, which is a different study design than what we did which is a matched case-control

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study. And the issues related to clinical trials and statistics are, although similar in that the same tools are used, some of the theoretical issues involved in clinical trials, i.e, subgroup analyses, but particularly interim analyses and endpoint analyses are different.
In fact, the paper, Schulz, Exhibit Number 22, leaves open the possibility that while subgroup analyses are problematic, tests for statistical interaction, which is what we did in our study, there is a place for them when done appropriately. So it's important to differentiate subgroup analyses in the context of a clinical trial from issues of statistical interaction in an observational study.
Q And when you describe an observational study, your case-control study is an observational study; is that correct?
A That's correct.
Q You mentioned that you had read in preparing for your report and doing your research you were familiar with the case reports or case series that have been published on this issue, correct?
A That's correct.

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Q Have you ever heard the statement that a case report or a case series is just one-half of a case-control study?
A I do believe I have used -- I have said that myself, yes, sir.
Q And is it a fair statement that case controls -- I mean, case reports and case series are one-half of a case-control study?
A They are the case part of it, yes, sir.
Q And those can play an important factor when combined with other evidence -- pharmacologic, plausibility, epidemiology, anecdotal reports -- in determining whether or not there is an association between a disease and a particular actor?
A My personal opinion is that case reports and case series aren't given their due weight in the field of epidemiology and in the field of medical research generally. They have a purpose of pointing out to clinicians unusual occurrences, but they also serve a role in epidemiology for generating hypotheses.
In the context of the discussion this morning, we are looking at the weight of

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evidence. And we discussed it for a brief amount of time the Hill criteria. And many of his original thoughts gave a lot more weight to these often discarded case reports and series.
Q We talked about a case-control study, and your study was a case-control study, correct?
A That's correct, a matched case-control study.
Q A matched case-control study. You described NAION earlier in the deposition as a rare event. Is that a fair statement that NAION is a --
A Oh, yes, sir.
Q And is there a particular reason why a case-control study is a medically and scientifically reasonable study to look at cause-and-effect relationships for rare events like NAION?
A Yes, although the term -- the phrase "cause and effect" --
Q Association.
A Okay.
Q I amend my question.
A Thank you. Rare diseases do not

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lend themselves to cohort studies. If we just do the math, a disease that has an incidence of one per hundred thousand would require us to have a sufficiently large cohort or be willing to sit around for a very long period of time to see enough events' outcomes of interest. The case-control design was originally developed to address this problem. It is the study design. It is the preferred study design for rare diseases such as NAION.

Q Are there any other examples where -- you will recall earlier there was a discussion about a hierarchy of epidemiological-type studies and observational studies and a hierarchy of those --

A Yes, sir.

Q -- and where case-control studies fit within that hierarchy, correct?

A Yes, sir.

Q But are there examples where case-control studies other than NAION have been accepted in the world of science and medicine as establishing a definite association between a disease and a particular act or event, drug, what have you?

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A There is an example that I often use in my introductory classes when we get to the discussion of case-control studies. It is often difficult for students to grasp rare, one in a hundred thousand, two in a hundred thousand. One of the papers I often give is -- there was a paper published in the New England Journal of Medicine early '80s about clear cell carcinoma of the vagina and exposure to DES which was a drug that was given to pregnant women. This a very small matched case-control study. The numbers elude me, but I want to say maybe there were 17 cases and an equal number of controls.

Clear cell carcinoma of the vagina is a very rare disease, and my recollection is foggy, but nearly all, maybe all but one of the cases was exposed and none of the controls were exposed. The relationship between the two was very, very clear. I'm not saying it was a cause-and-effect relationship, but that's often held up as, not only an example of a rare disease situation, but it is often held up as a situation where a case-control study has been used to identify, you know, a potentially at-risk medication.

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Q In light of the evidence that we've talked about today regarding Viagra and NAION, if a researcher, an epidemiologist, was to undertake a study about NAION, a case-control study, would it be scientifically reasonable and acceptable to include NAION -- I mean, to include use of ED medications like Viagra on the questionnaire today based on the evidence?

A Yes, sir, I believe it would be reasonable.

Q You've -- you were shown some evidence, some data from Pfizer that was published in the Gorkin-Sobel article, the Pfizer article, and you've looked at some of that data.

Does the data presented by Pfizer's expert demonstrate a lack of an association between Viagra and NAION at all?

A This is the -- some of the numbers that we discussed earlier, the three clinical trials, and we had this conversation earlier. They -- when one aggregates that data, there is an incidence rate that is arrived at. And in this particular paper, they use the background incidence which is derived from two of the other

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studies that we talked about. It is a very hard comparison to make. It's -- it's not a quantitative comparison, per se. There's no study design here. This is a -- it's partially a literature review. It's partially a -- so, to say that there's a statistical result here, to say that they demonstrate an association, they don't present the data in that way. They simply state that the aggregated data from these clinical trials -- oh, pardon me, one is a clinical trial, the other was a prospective study, the other was a retrospective study. Sorry -- are similar. If your question is is there an association, I think as I responded --

Q My question was does their data show a lack of association?

A No, it does not.

MR. OVERHOLTZ: That's all I have.

THE COURT: Mr. Slonim, anything else?

MR. SLONIM: No.

THE COURT: Mr. Becnel?

MR. BECNEL: No, sir.

VIDEOGRAPHER: Nothing further? The time is 2:27. This concludes Tape Number 6 and

the deposition of Dr. McGwin. We are off the record.

(End of deposition.)

CERTIFICATE

STATE OF ALABAMA)
JEFFERSON COUNTY)

I hereby certify that the above and foregoing deposition was taken down by me in stenotype, and the questions and answers thereto were reduced to computer print under my supervision, and that the foregoing represents a true and correct transcript of the deposition given by said witness upon said hearing.

I further certify that I am neither of counsel nor of kin to the parties to the action, nor am I in anywise interested in the result of said cause.

_____
Carrie M. Robinson, Commissioner